

REGION 5

**INSTRUCTIONS
ON THE PREPARATION OF
A SUPERFUND DIVISION
QUALITY ASSURANCE
PROJECT PLAN**

BASED ON EPA QA/R-5

REVISION 0

JUNE 2000

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REFERENCES

1. Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs, American National Standard, ANSI/ASQC E4-1994
2. EPA Requirements for Quality Management Plans, Interim Final, November 1999 (EPA QA/R-2)
3. EPA Quality System Description, August 1997 (EPA QA/G-0)
4. EPA Requirements for Quality Assurance Project Plans, Interim Final, November 1999 (EPA QA/R-5)
5. EPA Guidance for Quality Assurance Project Plans, Final, February 1998 (EPA QA/G-5)
6. Guidance for Data Quality Objectives Process, Final, September 1994 (EPA QA/G-4)
7. Data Quality Objectives Process for Hazardous Waste Site Investigations, Final, January 2000 (EPA QA/G-4HW)
8. Guidance for the Preparation of Standard Operating Procedures for Quality-Related Documents, Final, November 1995 (EPA QA/G-6)
9. Guidance for Data Quality Assessment: Practical Methods for Data Analysis, Final, January 1998 (EPA QA/G-9)
10. Policy and Program Requirements for the Mandatory Agency-Wide Quality System, EPA Order 5360.1 Change 1, July 1998
11. EPA Specifications and Guidance for Contaminant-Free Sample Containers, December 1992

References 2 - 9 are available at the website: <http://epa.gov/quality>

LIST OF ACRONYMS/ABBREVIATIONS

ARARs	Applicable or Relevant and Appropriate Requirements
ASTM	American Standards for Testing Materials
BNA	Base-Neutral-Acid Extractables (Semivolatile Organics)
BPM	Brownfield Project Manager
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act (Superfund)
COC	Chain of Custody
CLP	Contract Laboratory Program
CRDL	Contract Required Detection Limits
CRQL	Contract Required Quantitation Limits
CRL	Central Regional Laboratory
DCF	Document Control Format
DQO	Data Quality Objective
EMSL	Environmental Monitoring and Support Laboratory
EAPM	Early Action Project Manager
FSP	Field Sampling Plan
FSS	Field Services Section
MDLs	Method Detection Limits
MS/MSD	Matrix Spike/Matrix Spike Duplicate
NIST	National Institute of Standard Technology
NPL	National Priorities List
OSC	On-Scene Coordinator
QA/QC	Quality Assurance/Quality Control
QAMP	Quality Assurance Management Plan
QAPP	Quality Assurance Project Plan
QLs	Quantitation Limits
PARCC	Precision, Accuracy, Representativeness, Completeness, and Comparability
PE	Performance Evaluation Sample
RAS	Routine Analytical Services
RCRA	Resource Conservation and Recovery Act
RI/FS	Remedial Investigation/Feasibility Study
RD/RA	Remedial Design/Remedial Action
RPD	Relative Percent Difference
RPM	Remedial Project Manager
SAP	Sampling and Analysis Plan
SARA	Superfund Amendments and Reauthorization Act
SAS	Special Analytical Services
SF	Superfund
SMC	Sample Management Coordinator
SOP	Standard Operating Procedure
SOW	Statement of Work
SW-846	Test Methods for Evaluating Solid Waste
TAL	Target Analytes List
TCL	Target Compound List
TIC	Tentatively Identified Compound
TSA	Technical System Audit
USEPA	United States Environmental Protection Agency
VOA	Volatile Organic Analysis
VOC	Volatile Organic Compound

INTRODUCTION

U.S. Environmental Protection Agency (EPA) policy requires that all work performed by or on behalf of EPA involving the collection of environmental data will be implemented in accordance with an Agency-approved Quality Assurance Project Plan (QAPP). This requirement is defined in Policy and Program Requirements for the Mandatory Agency-wide Quality System, EPA Order 5360.1 CHG 1 (July 1998) for EPA organizations. A QAPP is a planning document that provides a “blueprint” for obtaining the type and quality of data needed to support environmental decision making. The QAPP integrates all technical and quality aspects of a project. The QAPP documents all quality assurance (QA), quality control (QC) and technical activities and procedures associated with planning, implementing and assessing environmental data collection operations. QA is an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client. QC is the overall system of technical activities that measures the attributes and performance of process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality. The system of activities and checks used to ensure that measurement systems are maintained within prescribed limits, providing protection against “out of control” conditions and ensuring the results are of acceptable quality.

The following document has been prepared by Region 5 to facilitate preparation of a QAPP based on the EPA Requirements for Quality Assurance Project Plans, November 1999 (EPA QA/R-5), EPA Guidance for Quality Assurance Project Plans, February 1998 (EPA QA/G-5) and Region 5 Superfund (SF) Division requirements. In accordance with EPA QA/R-5, there are four basic groups of elements that must be addressed in a QAPP. The four groups of elements and their intent are summarized as follows:

- A. Project Management - The elements in this group cover all aspects of project management, objectives and history. They identify the roles and responsibilities of project personnel and describe the communication procedures. These elements document that the project has a defined goal and that participants understand the goal and approach to be used.
- B. Data Generation and Acquisition - The elements in this group describe the design and implementation of all measurement systems that will be used during the project. All sampling procedures, analytical methods/procedures, and data handling and documentation procedures are described completely. If standard operating procedures (SOPs) exist, then they are referenced and included as attachments to the QAPP. All quality control procedures, frequency requirements, acceptance criteria, and corrective action procedures associated with all methods/procedures are documented.
- C. Assessment/Oversight - The elements in this group cover the procedures used to ensure

proper implementation of the QAPP.

- D. Data Validation and Usability - The elements in this group cover the QA activities that occur after the data collection phase of the project is completed. Implementation of these elements ensures that the data conform to the specified criteria, thus achieving the project objectives.

A crosswalk between EPA QA/R-5 and the previously used QAMS-005/80 can be found in Attachment B of the Region 5 SF QAPP Instructions.

Since the content and level of detail in individual QAPPs will vary according to the work being performed and the intended use of the data, Region 5 Superfund Division supports a “graded approach” when preparing QAPPs. In other words, the degree of documentation and detail will vary based upon the complexity and cost of the project. Appropriate consideration should be given to the significance of the environmental problem to be investigated, the environmental decision to be made, and the impact on human health and environment.

Basically a QAPP will fit into one of the following categories: project specific or generic program/multi-site QAPP. Both types of the SF QAPPs must be composed of all four elements.

- A “project-specific QAPP” provides a QA “blueprint” specific to one project or task. Project-specific QAPPs are used when projects are limited in scope and time and, generally can be considered the Sampling and Analysis Plan for the project.
- A “generic program or multi-site QAPP” is an overarching plan that describes a program’s quality objectives, and documents the comprehensive set of sampling, analysis, QA/QC, data validation and assessment, and Standard Operating Procedures (SOPs) specific to one program or group. In contrast to the project-specific QAPP, the generic program QAPP addresses the general, common activities of a program that are to be conducted at multiple locations or over a long period of time; for example, it may be useful for a large monitoring program that uses the same methodology at different locations or at the Brownfields projects. Project or task specific information, not covered by the “generic” QAPP document, is documented in detailed Sampling and Analysis Plans/Work Plans, which use the generic program QAPP as an informational reference whenever appropriate. A generic QAPP will be reviewed periodically to ensure that its content continues to be valid and applicable over time. The format described in the Instructions should be used for “generic program or multi-site QAPP” preparation.

It is recommended that generic program QAPPs and project -specific QAPPs be prepared using the format described in the Instructions and titled accordingly. However, if some of the required QAPP elements are incorporated into other project planning documents (such as Sampling and Analysis Plans, Field Sampling Plans, Field Operation Plans, or General Project Work Plans), then these documents can be referenced and submitted for the review at the time of QAPP submission.

A cross-reference table must be provided to identify where each required QAPP element is located in the inclusive project document. The reference location must be exact and must specify the complete document title, date, section number, page numbers, and location of the information in the inclusive document.

The pre-QAPP meeting/conference call should be held prior to the QAPP development. The QAPP should undergo internal review at all levels. The QAPP preparer is responsible for insuring that the QAPP is accurate and complete. The QAPP preparer should require that organizational personnel, contractors, and subcontractors review applicable sections of the QAPP prior to submitting it to Region 5 SF Division with the signature page.

The Project Manager (RPM, OSC, BPM, etc.) is responsible for screening of the project QAPPs before submitting for the review by Field Services Section (FSS) chemists. The checklist in Attachment B should be used as a screening tool. If the Project Manager found numerous deficiencies in the QAPP, it should be sent back to QAPP preparer without a chemist's review. If the QAPP has minor deficiencies, the document should be submitted for review with the QAPP Review Request Form (Attachment B).

All comments provided by chemists and other delegated approval authority must be acceptably addressed in writing prior to the beginning of field activities. All revisions to the original document should be identified. See item 13 of "DOs and DON'Ts" to facilitate QAPP approval. The approved SF QAPP must be implemented as prescribed, however, it is not intended to be inflexible or restrictive. When the original approved procedures are altered in response to project needs, such as, a change of the laboratory, additional sampling, or additional analysis, the QAPP must be amended. This amendment must be reviewed and approved in the same manners as the original QAPP. The amendment should contain complete identifying information, as presented on the original QAPP: Title and Approval Page, with updated signature and dates. Only after the amendment has been approved can the change be implemented.

It is essential that the QAPP be kept current and that all personnel involved in the work have easy access to the current version of the QAPP. For programs or projects of long duration, such as multi-year monitoring programs or ongoing sampling, the QAPPs will be reviewed at least annually by the Project Manager. If revisions are necessary to reflect current needs, the QAPP must be revised and resubmitted for review and approval.

The following document has been prepared by Region 5 to facilitate preparation of a QAPP based on the EPA Requirements for QAPPs for Environmental Data Operations, (EPA QA/R-5) and Region 5 requirements. This document is intended to serve as a tool for the preparation, review and approval of QAPPs for wide varieties of Superfund enforcement-lead, fund-lead, Federal Facilities, and state-lead site projects.

This document replaces "Region 5 Model Superfund Quality Assurance Project Plan," dated May 1996.

DOs AND DON'Ts TO FACILITATE QAPP APPROVAL

1. **DO** use QAPP checklist to review the document before submittal to FSS.
2. **DO NOT** submit the laboratory quality assurance program plan attached in an appendix in order to satisfy project-specific quality assurance project plan (QAPP) information. The generic lab QAPPs contain extraneous and ambiguous tables and information.

DO append or otherwise incorporate into the QAPP the laboratory information that is project-specific (e.g., laboratory chain of custody, internal performance and system audits, etc.) to address certain elements outlined in this document. For fund-lead projects the most current CLP Statements of Work must be followed, if the CLP is used.
3. **DO NOT** submit photocopied pages from Test Methods for Evaluating Solid Waste (SW-846) as laboratory Standard Operating Procedures (SOPs).

DO submit laboratory-specific SOPs for review if CLP SOW procedures are not to be used.
4. **DO NOT** submit copies of manufacturers' guides to operating instrumentation such as the field equipment commonly used to detect volatile organic analytes, or for the measurement of temperature, pH, Eh, and specific conductance.

DO submit the operator's SOPs for calibrating and maintaining such instruments.
5. **DO NOT** submit a multiple choice list indicating which methods will be used to analyze certain hazardous constituents. Only the instrumental and preparatory/cleanup/extraction/digestion procedures that will actually be utilized for analysis must be indicated in the QAPP. If SW-846 offers a selection of possibilities for performing the analyses, then the QAPP must specify which methods will actually be used.
6. **DO NOT** submit a QAPP to the U.S. EPA for review until a laboratory has been selected for a project. Once a selection has been made, you should discuss any potential changes in the laboratories with QA reviewers, since plans for a laboratory audit may be under way by EPA.
7. **DO NOT** write the QAPP until a scoping meeting/conference call has been held. This meeting involves representatives of the laboratory, the state agency, the Potentially Responsible Party (PRP), the contractor, and the U.S. EPA Project Manager and support staff (chemist, toxicologist, ecologist, geologist, safety specialist, etc.) for the purpose of defining project objectives and evaluating potential Quality Assurance problems during implementation of the Work Plan.
8. **DO** provide in the QAPP the complete list of hazardous constituents to be measured and reported for the site, including project's action limits. Such lists should be consistent with those constituent lists for which the methods have been provided in the QAPP.
9. **DO** provide information on the use of sample tags, if applicable. Sample tags are required for

- * Project Name; * Revision Date;
 * QAPP, FSP or Work Plan; * Section/Element;
 * Revision Number (First Submission should be considered "0") * Page Number

GROUP A: PROJECT MANAGEMENT

This element covers all aspects of project management, objectives and history. It identifies the roles and responsibilities of project personnel and describes communication procedures.

INSTRUCTIONS for TITLE and APPROVAL PAGE ***Element A1***

All QAPPs, including those prepared by non-EPA organizations, must be approved before implementation. **None of the environmental work addressed by the QAPP should be started until the initial QAPP has been approved and distributed to project personnel.** The QAPP must contain a Title and Approval Page. This title page will document the following:

- 1) The complete title of the project (multi-site, program specific, etc.) and activity (RI/FS; RD/RA, etc.) specifying the location (city, state) of the site;
- 2) The organization (State agency or consultant) that prepared the plan as well as the organization for whom it was prepared;
- 3) The date and the revision number (the initial draft should be considered Revision 0 and subsequent revisions as Revision 1, 2 etc.); and
- 4) Signature space with the title and date should be included for the individuals who have reviewed and approved the document.

Functionally, this page ensures that the desired content and level of detail are achieved through the review and approval (at a minimum) by the following personnel:

- A. For Fund-lead projects:
 - U.S. EPA Region 5, Remedial Project Manager (RPM), On-Scene Coordinator (OSC), Brownfields Project Manager (BPM), Early Action Project Manager (EAPM), etc.
 - U.S. EPA Region 5, Quality Assurance Reviewer (as necessary)
 - Contractor Project Manager
 - Contractor sampling organization
 - Responsible EPA contract laboratories (excluding CLP laboratories for CLP analysis and Region 5 Central Regional Laboratory (CRL) for any routine analysis).
- B. For enforcement-lead and Federal Facilities projects:

- U.S. EPA Region 5, Remedial Project Manager (RPM)/On-Scene Coordinator (OSC)
- U.S. EPA Region 5, Quality Assurance Reviewer (as necessary)
- Contractor Project Manager/Federal Facility Manager
- Contractor Quality Assurance Manager
- Contract Laboratory Directors
- Sampling Contractors

NOTE: The titles and names of all individuals appearing on the title page will be consistent with the references to these people elsewhere in the QAPP (e.g., project organization, corrective action, and QA reports to management sections). See Figure 1 as an example of the Signature page in Attachment A.

INSTRUCTIONS for TABLE OF CONTENTS AND DOCUMENT CONTROL FORMAT
Element A2

A. *Table of Contents*

All QAPP sections, tables, figures, and appendices (and contents of individual appendices) will be included in a Table of Contents. All subsections will be numbered. Additionally, the QAPP Table of Contents will address each of the following items:

1. A serial listing of all QAPP elements will be presented according to the structure indicated in the Table of Contents.
2. A listing of any appendices and subsections, which are referenced in the QAPP (i.e., standard operating procedures (SOPs), summaries of past data, etc.), will be presented.
3. Following the list of appendices, a listing of any tables and figures that are required to augment the QAPP requirements will be presented.
4. A list of acronyms/abbreviations will be provided.

B. *Document Control Format (DCF)*

Page numbers will be added to the Table of Contents of the submitted QAPP. Furthermore, within the body of the submitted QAPP, page numbers will be presented in accordance with the Document Control Format (DCF). A DCF should be used to individually paginate each QAPP element to facilitate revisions as well as ensure that no pages are missing. The DCF to be placed

in the upper right-hand corner of each page will include:

- Project Name
- QAPP, FSP or Work Plan
- Revision Number
- Revision Date
- Section/Element
- Page Number

The Project Name may be shortened or abridged as necessary. The Page Number will be stated relative to the total number in the section (e.g., Section 4, Page 2 of 8). A new QAPP section will be started at page one. All other documents, which are referenced in the QAPP (Work Plan, Field Sampling Plan, etc.) and have become a part of the QAPP by such reference, should also include the DCF.

This component, together with the distribution list (see Element A3), facilitates control of the document to help to ensure that the most current QAPP is in use by all project participants. Each revision of the QAPP should have a different revision number and date.

INSTRUCTIONS for DISTRIBUTION LIST
Element A3

List all the individuals and their organizations that will receive copies of the approved QAPP and any subsequent revisions. Include all persons who are responsible for the implementation, including managers. The distribution list together with document control information will help the project manager ensure that all key personnel in implementation of the QAPP have up-to-date copies of the plan.

INSTRUCTIONS for PROJECT/TASK ORGANIZATION
Element A4

This element should identify the individuals or organizations participating in the project and discuss their specific roles and responsibilities. The principal data users, the decision-makers, the project Quality Assurance Manager and persons responsible for implementation must be identified. The project QA manager must be independent of the unit generating the data. (This does not include being independent of senior officials, such as corporate managers or agency administrators, who are nominally, but not functionally, involved in data generation, data use, or decision-making). The following should be included in Element A4:

A. Management Responsibilities

All managers who will have some responsibility in this project will be identified and their responsibilities will be specifically defined. This includes the PRPs, their contractors, U.S. EPA,

and State management (if applicable).

The RPM, OSC, EAPM, or BPM is responsible for directing and/or overseeing and coordinating all project activities. He or she is responsible for submitting QAPP and QAPP revisions and amendments to appropriate personnel for review and approval.

The Project manager should assemble a team consisting of technical personnel including data generators, QA scientists, and data users to plan the project. The size of the team should reflect the complexity of the project. The team defines the quality of the data by setting the acceptability limits, otherwise known as measurement performance criteria. Once the measurement performance criteria are known, the team can select the sampling and analytical methods that have appropriate quantitation limits and quality control limits to achieve Data Quality Objectives (DQOs) for the project.

B. QA Responsibilities

The responsibilities of all QA personnel involved in this project will be identified by position and their responsibilities will be delineated. As part of the detail of this section, the QA personnel responsible for the following will be specified:

- QAPP Review and Approval
- Data validation
- Data assessment
- Internal and external performance and system audits

Field Services Section chemists are responsible for review/approval of the submitted QAPPs.

C. Field Responsibilities

The responsibilities of the field personnel will be outlined in this section. Included in this section will be the person responsible for identifying and documenting nonconformance and subsequent corrective action.

D. Laboratory Responsibilities

Laboratory responsibilities will be outlined in this section. This includes stating the name and location of the non-CLP laboratory (city and state) and listing the analytes and matrices that will be tested at the laboratory. Any lab staff with responsibility during this project will have those duties stated (e.g., lab sample custodian, etc.).

E. Special Training Requirements/Certification

Identify and describe any specialized training or certification requirements needed by personnel in

order to successfully complete the project or task. Discuss how such training will be provided and how the necessary skills will be assured and documented.

F. Project Organization Chart

Provide a concise organizational chart showing the relationships and the lines of communication among all project participants, including the EPA. Include other data users who are outside of the organization generating the data, but for whom the data are nevertheless intended. The organization chart must also identify any subcontractor relationships relevant to environmental data operations. See Figure 2 of Attachment A.

INSTRUCTION for PROBLEM DEFINITION/BACKGROUND INFORMATION
Element A5

In this element of the QAPP, the overall specific problems to be solved or decisions to be made should be explained. This should be a succinct description of the project, including a brief statement addressing the phase(s) of the work and intended objectives of the investigation. The section should answer the basic questions, "What is the purpose of the work effort?"

The background information provided in this element should place the problem in historical perspective, giving the readers and users of the QAPP a sense of the project's purpose. The chronological history of the site leading to its current status under CERCLA should be outlined, including current site ownership, if known. Documentation of waste streams managed and releases known to have occurred on-site, a summary of any previous sampling and analysis efforts and data with an overview of these results or copies of previous reports should be appended to the QAPP or this information can be referenced from other documents (including specific section(s) and page numbers) submitted for the review. Site histories are unique and often there are large historical gaps. Usually, much of the known information has already been gathered. Data with an overview of the results or copy of previous data reports for the site can be appended to the QAPP.

This element should focus on a description of site-specific features, including location, size, borders, important physical features, topographic, geological and hydrogeological information. Each of these items should be clearly addressed. The QAPP preparer should also consider whether there are any unique or special site-specific features of any kind, which may have some later bearing on the way in which data is obtained.

The following information should be summarized in this section:

- The problem to be addressed by the project. For example, "Residential drinking water wells in Mudtown have shown increasing levels of lead over the past year."
- The environmental questions being asked. For example, "What is the source of lead

contamination in the residential drinking water wells in Mudtown?”

- Include existing site conditions. Information, such as soil staining, and presence of free product materials, odors and other known hazards, should be identified and their location should be specified. Physical objects, such as metallic debris, drums, processing equipment should be identified and their location on the site specified.
- References to existing reports, e.g., monitoring reports and/or remedial investigation/or phase I or II reports/remedial action reports that describe site conditions and indicator chemicals for long-term remediation should be provided.
- The past and current chemical use information discussed in this section will be the basis for deciding on the contaminants of concern to be investigated during the project.
- The rationale for inclusion of chemical and nonchemical analysis.
- The site maps should be provided/referenced in this section.

Note that the problem statement is the first step of the Data Quality Objectives (DQOs) Process and the decision specification is the second step of the DQO process. The DQO Process is explained in detail in Element A7A.

INSTRUCTIONS for PROJECT/TASK DESCRIPTION AND SCHEDULE
Element A6

This element of the QAPP provides a general overview of the activities that will be performed and how and when they will be performed based upon background information/data, pre-planning site visits, and pre-QAPP/scoping meetings/conference calls. Specific details for individual project activities will be discussed in later sections.

A. The following tasks should be established for each project:

- Task 1. This QAPP should represent the results of initial project planning as summarized by the DQO process. However, the project planning/DQO process is iterative, and the DQOs and this QAPP will be revised if warranted by information developed through execution of this project. Project planning meetings are key to the success of any project and should be held by the team prior to QAPP preparation. Planning meetings are held to define the purpose and expected results of the project; the environmental decisions that need to be made; the project quality objectives necessary to achieve expected results and support environmental decisions; the sampling, analytical and data assessment activities that will be performed; and the final products and deliverables for the project. Project planning results in reaching agreement by the team on the purpose of the project; the environmental questions that are being asked; and the environmental decisions that must be made. The team determines criteria for how “good” the measurement data must be and documents those measurement performance criteria in Element A7B of the QAPP.
- Task 2. Target compounds and parameters must be described, when known. The QAPP preparer must provide a separate table for each matrix, concentration level and analytical parameter. These tables should include Project Required Action Limits and quantitation limits. Project Required Quantitation Limits and Action Limits must be established prior to the selection of sampling and analytical methods. To compensate for potential analytical inaccuracy at the quantitation limit, it is recommended that if possible the Project Required Quantitation Limits should be at least two to five times less than Action Limits. The quantitation limits from individual methods and laboratories are evaluated relative to project required Action Limits to determine their suitability to meet project quality objectives. If the published method quantitation limit exceeds the Action Limit for the contaminant of concern or other target analyte, then that analytical method is unacceptable for the analysis of that analyte. Use Table 1 of Attachment A as an example.
- Task 3. Briefly explain the rationale for sampling specific matrices, concentration levels and analytical parameters of concern and the rationale for the sampling design

selected (including the logic used to determine sample locations and the type, number and frequency of field samples). Refer sample locations to historical and current site maps. Include any additional maps, if necessary, to delineate site boundaries geographically, horizontally and vertically. Provide complete details for the sampling rationale, process design and sampling tasks in Element B1. Briefly describe the sampling methods that will be used. Describe any new or innovative sampling techniques that will be employed. Provide a complete description of the sampling methods and associated sampling quality control, and identify all sampling, sample handling, and custody SOPs in Elements B2 and B3 of the QAPP. Summarize by matrix, the number of field and QC samples that will be collected for each analytical parameter and concentration level. Use Table 2 of Attachment A as an example.

- Task 4. Describe briefly the analytical task to be performed including the sample matrices, analytical parameters, concentration levels and general description of analytical methods. Clearly differentiate analytical tasks that will be performed in the field from those performed in the fixed laboratory. Describe any new or innovative analytical techniques that will be employed and explain how the new technique will provide improved data over traditional/standard methods. Also, describe any specialized equipment and/or analysis that will be required. Provide complete detailed description of the analytical tasks and associated quality control, and identify all analytical SOPs and methods in Element B4 of the QAPP. Identify the analytical services that will be provided for this project: organizations/ laboratories that will provide the analytical services (for all field screening, field analytical and fixed laboratory analytical work, including all prime laboratories, subcontractor laboratories and backup laboratories) by matrix, analytical parameter and concentration level.
- Task 5. Briefly discuss how data will be verified internally and validated externally and how analytical error will be assessed. Region 5 recommends that all data be validated prior to use in environmental decision making. The data validation criteria and guidance used to validate the project data should be identified in this section. If data will not be validated, then document this fact and provide justification in this section. Provide a complete description of the data verification and validation tasks and procedures in Element D1 of the QAPP.
- Task 6. Include a short description of the quality assurance assessments that will be performed during the course of the project and the frequency at which each will be performed. If assessments are not planned, then document this fact and provide justification in this section. Provide a complete description of the planned assessments in Element C1 of the QAPP.
- Task 7. Include a short description of how validated project data will be reconciled with

the project Data Quality Objectives (DQO). Provide a complete description of data usability assessment and reconciliation process in Element D3 of the QAPP.

Task 8. Summarize the project documents, records and reports that will be compiled and/or generated as part of the project and those that will be maintained in the site files. Itemize and describe all project documents, record, and reports that will be compiled and /or generated during the course of the project in Element C2 of the QAPP.

B. *Project Schedule.* Provide a schedule of work to be performed in graphical or tabular format. The time line must include the start and completion dates for all project activities. Include the quality assurance assessments that will be performed during the course of the project. Schedule sufficient time for document review and implementation of effective corrective actions. Describe the procedures for notification of project participants concerning project schedule delays. Identify, by job function and organization name, the personnel responsible for providing as well as receiving such notification, and the personnel responsible for approving schedule delays.

Discuss all resource and time constraints, and identify all regulatory requirements and/or restrictions, that will impact the project schedule. Discuss all seasonal sampling restrictions and considerations.

The use of bar charts showing time frames of various QAPP activities is recommended. Use Figure 4 of Attachment A as an example.

INSTRUCTION for QUALITY OBJECTIVES and CRITERIA for MEASUREMENT DATA
Element A7

The purpose of this element is to document the DQOs of the project and to establish performance criteria for the mandatory systematic planning process and measurement system that will be employed in generating the data.

A. Data Quality Objectives (DQOs) Process

DQOs are qualitative and quantitative statements that clearly state the objective of a proposed project; define the most appropriate type of data to collect; determine the most appropriate conditions for data collection; and specify acceptable decision error limits that establish the quantity and quality of data needed for decision making. The following description of the DQO process is based upon Guidance for Data Quality Objective Process (EPA QA/G-4).

Do not describe the DQOs by analytical level! In the past DQOs have been mistakenly described as one to five data quality levels. **These levels are not to be used for any Region 5 SF projects.** These levels describe analytical methods, not DQOs. For example, the previously

defined “Level II” field analyses have the potential to produce fully defensible data that can be used to achieve a variety of project-specific data quality objectives.

The DQO process is a strategic planning approach that is designed to ensure that the type, quantity, and quality of environmental data used in decision making are appropriate for the intended application. DQOs provide a systematic procedure for defining the criteria that a data collection design should address when to collect samples, where to collect samples, number of samples to collect, and tolerable levels of decision error.

The DQO process has both a quantitative and a qualitative statement associated with the data collection activities. The quantitative aspect seeks to use statistics to design the most efficient field investigation that limits the possibility of making an incorrect decision. The qualitative aspect seeks to encourage good planning for field investigations and complements the statistical design.

DQO process outputs, including acceptable limits on decision errors, provide the information necessary to develop field investigations, statistical sampling designs, and sampling and analysis plans (SAPs) for a site. By using the DQO process, the scoping team establishes criteria for determining when data are sufficient for site decisions. This provides a stopping rule—a way for the management team to determine when they have collected enough data. In addition, the DQO process assists the project team to establish an adequate level of data review/validation and documentation.

The DQO process is a valuable tool that offers several advantages. It focuses studies by clarifying vague objectives and limiting the number of decisions that must be made. The process enables data users and technical experts to specify data requirements prior to collection events. It provides a convenient way to document activities and decisions; to communicate the data collection design to others; and to give the data user confidence that the data collected support the decisions concerning remediation and redevelopment of the site. Finally, the DQO process is designed to save resources by streamlining the study process and making data collection operations more resource-effective.

The DQO process is described below in a series of seven sequential steps. See Figure 3 and Table 3 of the Attachment A. The overall DQO process provides a logical framework for planning multiple field investigations, which should prove useful for those municipalities and Tribal governments attempting to prioritize candidate sites for redevelopment.

Step 1: Stating the Problem

The first step of any decision making process is to define the problem that has initiated the study. The goal of this step is to create a well-structured team of technical experts and stakeholders that will work effectively to develop a concise and complete description of the problem, which will provide the basis for the rest of the DQO development.

Identifying members of the scoping team—the group that will develop DQOs for the study—is a critical initial action. Project scoping is perhaps the most critical component of the site assessment process, as it allows team members to fully determine the scope of sampling events. Therefore, it is important that all vested parties (including project managers, engineers, chemists, toxicologists, ecologists, field sampling personnel, and local government officials) be involved in the project from the conceptual design stage, and that all team members have clearly defined roles and responsibilities throughout the project. Roles and responsibilities for the scoping team should be captured in the site-specific QAPP.

The scoping team will collect and evaluate historical site data to develop a conceptual site model. Developing a site model means that the project team can generally reconstruct what went on at the site and how chemicals were used and disposed. The conceptual site model will identify the relationships between types and concentrations of contamination; locations where contamination or contamination/waste sources exist; potentially contaminated media and migration pathways; and potential physical and environmental targets or receptors. Information gathered from the conceptual site model is used to define site conditions that indicate or could lead to an unacceptable threat or exposure at the site.

The scoping team should follow each step of the DQO process for each medium (e.g., soil, groundwater) of concern. Therefore, it is important, if possible, that the scoping team includes representatives knowledgeable in quality assurance, sampling techniques, statistical modeling, technical project management, human health and ecological risk assessments, chemistry, toxicology, biology, ecology, data management and natural resource management. Once the scoping team has gone through the process completely for one medium, it becomes easier and quicker to develop additional sets of DQOs for other media.

Stating the problem typically involves developing a concise description of the problem to be addressed. The problem statement should include the regulatory and programmatic context of the problem, such as the regulatory objectives and basis for the field investigation. A description of the source and/or location of contamination, such as physical and chemical factors associated with the site that could result in contaminant release or unacceptable exposures should be included. The problem definition also should include appropriate action levels for evaluating and responding to releases or exposures, and appropriate response actions.

Finally, the problem statement should, if appropriate, specify available resources and relevant deadlines for the study. This description should include the anticipated budget, available personnel, and contractual vehicles (if applicable). A time line should be developed that shows deadlines for completion of the study and any intermediate deadlines that may need to be met.

Step 2: Identifying the Decision

The purpose of this step is to define the decision statement that the study will attempt to resolve and identify the alternative actions that may be taken based on the outcome of the study. The

combination of these two elements is called the decision statement; the decision statement is critical for defining decision performance criteria later in the DQO process. The principal study question should be stated as specifically as possible. Alternative actions, including the no action alternative, should also be clearly defined, as these will form the basis for defining decision performance criteria later in the process (see *Step 6: Specifying Limits on Decision Errors*).

The decision statement should express a choice among alternative actions. A suggested format is: “Determine whether or not [unknown environmental conditions/criteria from the principle study question] require/support [taking alternative actions].” If several such decisions will be made, each decision should be identified and a relationship established among them that also indicates the order of priority.

Step 3: Identifying Inputs to the Decision

The scoping team must identify the different types of information that will be needed to resolve the decision statement. For example, it is important to determine whether monitoring, modeling, or a combination of these approaches will be used to support the decision, as each approach requires specific inputs.

Sources may already exist that can help the project team, including: historical records; regulations; directives; engineering standards; scientific standards; scientific literature; previous site field investigations; or professional judgements. All existing data should be qualitatively evaluated to determine if it is appropriate for the study.

Next, the team must define the action level, or threshold value, that provides the criterion for choosing among alternative actions. Regulatory thresholds or standards usually form the basis for action levels. If no regulatory threshold or standard can be identified for site contaminants during this step, the scoping team needs to identify information needed to develop a realistic concentration goal to serve as a contaminant action level for the field investigation design and evaluation. The final numerical value for the action level is determined as part of *Step 5: Developing a Decision Rule*, and the decision on which analytical method will be used will be determined in a later step, *Step 7: Optimize the Design*.

The outputs for the activities above include a list of informational inputs needed to make the decision and a list of environmental variables or characteristics that will be measured. In essence, the outputs of this step are actually the inputs to the decision.

Step 4: Defining the Boundaries of the Study

The boundary of the study refers to both spatial and temporal boundaries. In order for samples to be representative of the area for which the decision will be made, the boundaries of the study must be precisely defined. Practical constraints that could interfere with sampling are also identified in this step. A practical constraint can be any obstacle that may interfere with the full

implementation of the study design.

To define the spatial boundary of the decision, the geographic area within which all decisions apply must be identified. Examples of spatial boundaries are property boundaries and potential exposure areas. Along with the identified geographic area, the total collection from which samples will be drawn, referred to as “population,” also needs to be identified. For example, soil sampling boundaries may include the population of the “surface or top 12 inches of soil,” and the “subsurface soil (soil from 12 to 24 inches deep)” taken from the southwest corner of the property where the chemical storage shed was once located.

The scale of decision making is the smallest area, volume, or time frame of the media for which the scoping team wishes to control decision errors. The size may range from the entire geographic boundaries of the site to the smallest size area that presents an exposure to the receptor (the chemical storage area in the previous example).

The temporal boundaries of the decision also should be defined. It may not be possible to collect data over the full time period to which the decision will apply. For example, a study to measure exposure to volatile organic compounds from a contaminated site may give misleading information if the sampling is conducted in the colder winter months rather than the warmer summer months. The scoping team would therefore have to determine the most appropriate period for gathering data that will reflect the conditions that are of interest.

Practical constraints on data collection also need to be recognized. These constraints include meteorological conditions when sampling is not possible; inability to gain site access or informed consent; or the unavailability of personnel, time, or equipment.

Step 5: Developing a Decision Rule

The purpose of developing a decision rule is to integrate the output from the previous steps of the DQO process into a statement that defines the parameter of interest; delineates the scale of decision making; specifies the action level; and describes the logical basis for choosing among alternative actions.

The action level is the contaminant threshold which, if exceeded, would indicate that the management team must select among the alternative actions identified earlier in the process. If the decision maker believes that the final remediation level could be one of two different levels, then the more stringent one should be chosen for the action level.

The output for this step is to develop an “if . . . then . . .” statement that defines the conditions that would cause the decision maker to choose among alternative courses of action. An example is: If the [parameter of interest] within the [scale of decision making] is greater than [the action level], then select [alternative action A]; otherwise select [alternative action B].

For example, the assessment identified an area that was previously used as a chemical storage

shed. Manifests indicate that large quantities of highly toxic solvents were stored in the structure. There is a need to determine if any of the chemicals were absorbed into the soil below and how deeply. It is also known that the State has a lower cleanup level than EPA. The decision rules could be “if the soil has concentrations of solvents greater than the State cleanup level at one to two feet, then the chemical storage area must be cleaned to state levels down to two feet.” This is the most conservative decision rule, and allows for additional decisions to be made for the top 12 inches of soil and comparison against the EPA standard.

Step 6: Specifying Limits on Decision Errors

The sampling process is not an exact representation of the site’s characteristics, but it is an estimate of the site’s state. Because of the inexact nature of sampling, decisions could be made that are based on inaccurate measurement data. Acceptable limits on the probability of making a decision error should be developed. These limits are incorporated into the sampling and analysis plan for site assessment.

The true value of an environmental measurement can be in question due to sampling error. Sampling errors can occur when sampling is unable to capture the complete scope of natural variability that exists in the environment. Data may also be questionable due to measurement errors. Measurement errors can happen during sample collection, handling, preparation, analysis, data reduction, or data handling. A combination of sampling and measurement error is called a total study error.

Often data may be suspect or questionable. There may be corrective steps that can be taken or additional qualifying information that can be collected that will allow the full or limited use of the data. These are called corrective actions, and some forethought should be given to determining corrective action scenarios during this step.

Step 7: Optimizing the Design

The purpose of this step is to identify the most resource-effective sampling design that generates data, which satisfy the DQOs specified in the preceding steps. In most cases, this decision involves the type and number of samples deemed necessary to characterize a site or an area of the site. Most field investigations will require a probabilistic sampling approach to use analytical results from a few samples to estimate the contamination on the entire site. The scoping team is expected to balance site assessment sampling with such resources as funding, personnel, and temporal constraints while still meeting the DQOs. In the chemical storage example, soil screening methods may be used to determine “hot spots,” or the locations within the study area where the highest concentrations of chemicals are expected.

For some field investigations, a non-probabilistic or judgmental sampling approach is acceptable. Typically, this occurs when a scoping team wants to confirm the existence of contamination at specific locations, based on historical or visual information.

The scoping team should review the outcomes of the previous DQO process steps to determine

exactly how the limits on decision errors will prescribe the number and location of samples to be collected and the types of analyses per sample. Based on these previous DQO outputs, the scoping team can then confirm the budget for sampling and analysis and the project schedule. Design options should be evaluated based on cost and ability to meet the DQO constraints in order to select the most resource-effective option. The chosen alternative may be the lowest cost alternative that meets DQOs, or it may be a relatively low cost design that still performs well when design assumptions change.

Once the final design has been selected, it is important to ensure that the design is properly documented. This will improve the efficiency and effectiveness of development of field sampling procedures, quality control procedures, and statistical procedures for data analysis. Table 3 of Attachment A provides examples of DQO process used for sites.

B. Measurement Performance Criteria - PARCC

Once the environmental decisions have been identified, data users and QA personnel can determine the project quality objectives, including the measurement performance criteria, that must be satisfied in order to support defensible decisions.

Document the performance criteria selected for the project-specific sampling measurement systems that will ensure those project objectives are met. For example, appropriate performance criteria should be identified to ensure that monitoring wells will be installed correctly and will yield representative samples.

Measurement performance for precision, accuracy, representativeness, completeness, and comparability (PARCC) should be determined for each matrix, analytical parameter, concentration level and analyte, if applicable. These parameters indicate the qualitative and quantitative degree of quality associated with measurement data and are also referred to as PARCC parameters.

Document the performance criteria selected for the analytical measurement systems that will ensure those project objectives are met. The following paragraphs provide examples of developing performance criteria for the project specific analytical measurement systems.

Precision: Determine quantitative measurement performance criteria for acceptable field and laboratory precision for each matrix, analytical parameter and concentration level. For Region 5 SF projects field duplicates should be collected at a rate of at least one duplicate per 20 investigative samples. In some cases it can be more frequent. The DQO process should clearly define this requirement. Also, determine analyte-specific measurement performance criteria, if applicable. Determine what QA/QC activities and/or QC check samples will be performed or analyzed to measure precision for each matrix, analytical parameter and concentration level.

Precision is the degree of agreement among repeated measurements of the same characteristic (analyte, parameter, etc.) under the same or similar conditions. Precision data indicate how consistent and reproducible the field sampling or analytical procedures have been. Comparing field and laboratory precision will help to identify sources of imprecision if a problem exists.

Duplicate precision is evaluated by calculating a Relative Percent Difference (RPD) using the following equation (the smaller RPD; the greater the precision):

$$RPD = \frac{S - D}{(S + D) / 2} \times 100$$

Where: S = First sample value (original or matrix spike value);
D = Second sample value (duplicate or matrix spike duplicate value)

Accuracy: Determine quantitative measurement performance criteria for acceptable accuracy for each matrix, analytical parameter and concentration level. Also, determine analyte specific measurement performance criteria, if applicable. Determine what QA/QC activities and/or QC checks or samples will be performed or analyzed to measure accuracy/bias for each matrix, analytical parameter and concentration level.

Accuracy is the extent of agreement between an observed value (sample results) and the accepted, or true, value of the parameter being measured. Analyte accuracy can be evaluated using different types of QC samples. For example, a Standard Reference Material (SRM) or Laboratory Control Sample (LCS), containing a known concentration of analyte(s) provide information about how accurately the laboratory (analysts, equipment, reagents, etc.) can analyze for a specific analyte(s) using a selected method. The laboratory and method accuracy are calculated as a percentage using the following equation (the higher the value, the greater the accuracy):

$$\text{Accuracy} = \frac{\text{Measured Value}}{\text{True Value}} \times 100$$

Because environmental samples contain interferences (i.e., other compounds that may interfere with the analysis of specific analyte), the accuracy for a specific analyte should be evaluated in relation to the sample matrix. This is done by analyzing matrix spike samples. A known concentration of analyte is added to an aliquot of the sample. The difference between the concentration of analyte in the unspiked sample and the concentration of the analyte in the spiked sample should be equal to the concentration of the analyte that was spiked into the sample. The spike recovery is calculated in percentage using the following equation:

$$\% \text{ Recovery Accuracy} = \frac{\text{Spiked Sample Conc.} - \text{Unspiked Sample Conc.}}{\text{Spiked Concentration added}} \times 100$$

Representativeness: Determine qualitative measurement performance criteria for acceptable representativeness for each matrix, analytical parameter and concentration level. Also, determine analyte-specific measurement performance criteria, if applicable. Determine what QA/QC activities and/or QC checks or samples will be performed or analyzed to measure representativeness for each matrix, analytical parameter and concentration level.

Representativeness is a qualitative term that describes the extent to which a sampling design adequately reflects the environmental conditions of the site. Representativeness also reflects the

ability of the sample team to collect samples and laboratory personnel to analyze those samples in such manners that the data generated accurately and precisely reflects the conditions at the site. In other words, a discrete sample (that is collected and then subsampled by the laboratory) is representative when its measured contaminant concentration equates to the contaminant concentration of some predefined vertical and horizontal spatial area at the site. Consider the issue of sample homogeneity, and sampling and subsampling variability, when developing criteria for representativeness. The use of the statistical sampling design and standardized SOPs for sample collection and analysis helps to ensure that samples are representative of site conditions.

Comparability: Determine quantitative measurement performance criteria for acceptable comparability for each matrix, analytical parameter and concentration level. Also, determine analyte-specific measurement performance criteria, if applicable. Determine what QA/QC activities and/or QC checks or samples will be performed or analyzed to measure comparability for each matrix, analytical parameter and concentration level.

Address such issues as consistency in sampling and analytical procedures within and between data sets. For example, monitoring well sampling SOPs should require that well casings be notched or permanently marked so that the water level measurement is taken from the same spot for each sampling event. This will help to ensure data comparability for repeated water level measurements.

Whenever full protocol analysis is performed to confirm field screening results, comparability criteria must be established and documented in the QAPP prior to data collection. Comparability criteria should be determined for each matrix, analytical parameter (and analyte, if applicable) and concentration level.

The comparability of field screening data generated on site and split sample confirmation data generated in fixed or field laboratory using conventional full protocol analytical methods are the most important factor for determining whether field screening data will meet the project objectives and be usable for project decision making. The conventional full protocol analytical methods that are used to confirm field screening results must be scientifically valid and well-documented methods that are used to confirm field screening results must be scientifically valid and well-documented methods that have been routinely accepted by regulators, since data comparability decisions are based upon a limited number of samples analyzed by those conventional full protocol methods.

Completeness: Determine quantitative measurement performance criteria for acceptable completeness for each matrix, analytical parameter and concentration level. Also, determine analyte-specific measurement performance criteria, if applicable. Identify which QA/QC activities will be performed to measure completeness.

Completeness is a measure of the amount of valid data collected using a measurement system. It is expressed as a percentage of number of valid measurements that should have been collected. For Region 5 SF projects the completeness should be at least 90% or greater. The DQO process should clearly define this requirement. Separate values should be provided for the whole data set

VS. critical data (a subset of the whole data set). Since lack of data completeness may require resampling and additional costs, discuss how sufficient data will be guaranteed for critical sample locations.

Sensitivity: Determine quantitative measurement performance criteria for acceptable sensitivity to ensure that Quantitation Limits can be routinely achieved for each matrix, analytical parameter and concentration level. Also, determine analyte-specific measurement performance criteria, if applicable. Identify which QA/QC activities and/or QC checks or samples will be performed or analyzed to measure sensitivity.

Sensitivity is the ability of the method or instrument to detect the contaminant of concern and other target compounds at the level of interest. Method and instrument sensitivity may be evaluated by preparing and analyzing a Laboratory Fortified Blank (LFB). A LFB is a blank matrix that is spiked at the Quantitation Limit with the contaminants of concern. Sensitivity may be measured by calculating the percent recovery of the analytes at the quantitation limit.

After measurement performance criteria have been established, the project manager, data generators and QA personnel can select sampling and analytical procedures/methods. They will select methods and procedures that have QC acceptance limits that support the achievement of established performance criteria. Concurrent with the development of measurement performance criteria and the selection of sampling and analytical procedures/methods should be the determination of analytical data validation criteria. Data user and QA personnel should select data validation criteria that support both the established project-specific measurement performance criteria and the analytical method/procedure QC acceptance limits. This will ensure that only data meeting project-required measurement performance criteria are used in decision making. Tables 4 and 5 of Attachment A may be used as an example in QC acceptance limits.

INSTRUCTIONS for SPECIAL TRAINING REQUIREMENTS/CERTIFICATION ***Element A8***

The purpose of this element is to ensure that any specialized training requirements necessary to complete the projects are known and furnished and the procedures are described in sufficient detail to ensure that the specific training skills can be verified, documented, and updated as necessary.

All project personnel *must* be qualified and experienced in the project task for which they are responsible. Certain projects require uniquely trained personnel to perform specialized field sampling, field or off-site laboratory analysis, data validation and other project functions. Depending on the nature of environmental data operation, the QAPP may need to address compliance with specifically mandated training requirements, other than Health and Safety. Health and Safety requirements will be covered in the site-specific Health and Safety Plan. If hazardous materials are moved offsite, compliance with the training requirements for shipping hazardous materials as mandated by Department of Transportation (DOT) may be necessary.

Organizations participating in the project are responsible for ensuring certification of the personnel. Training and certification should be planned well in advance for necessary personnel

prior to implementation of the project.

All certificates or documentation representing completion of specialized training should be maintained in personnel files. A table providing the special personnel training requirements including the dates when the training was taken can be included in the QAPP.

INSTRUCTIONS for DOCUMENTATION AND RECORDS
Element A9

This element identifies the documents and reports to be generated throughout the investigation and the information to be included in these documents and reports. A description of data management system established for the project, including a description of types of data that will be collected is presented in Element B10.

A. Documents and records that will be generated for all aspects of the project, including but not limited to:

1. Sample collection records show that the proper sampling protocol was performed in the field. This documentation should include the names of the persons conducting the activity, sample number, sample collection points, maps and diagram, equipment/methods used, climatic conditions, and unusual observations. Bond field notebooks should be used to record raw data and make references to prescribed procedures and changes in planned activities. They should be formatted to include pre-numbered pages with date and signature lines. Examples of field data collection sheets, Chain of Custody (COC) records, custody seals, and sample tags (if required) should be provided.
2. QC sample records document the generation of QC samples such as field, trip and equipment rinsate blanks and duplicate samples. They also include sample integrity and preservation.
3. Field analysis records should include the COC records, sample receipt forms/sample tracking forms, preparation and analysis forms and logbooks, tabulated data summary and raw data for field samples, standards, QC samples, corrective action reports. Itemize the required data package deliverables for all analytical data generated in the field.
4. Fixed laboratory records. The following list describes some of the laboratory-specific records that should be compiled if available and appropriate: COC records, sample receipt forms/sample tracking forms, preparation and analysis forms and/or logbooks, tabulated data summary forms and raw data for samples, standards, QC samples, corrective action reports.
5. Data handling records. These records document protocols used in data reduction, verification, and validation. Data reduction should address data transformation operations such as converting raw data into reportable quantities and units, use of significant figures, reporting extreme values, etc. Data verification ensures the accuracy of data transcription and calculations, if necessary, by checking a set of computer calculation manually. Data validation ensures that QC criteria have been met and data are appropriately qualified.

B. Data Reporting Package Format and Documentation Control

Discuss procedures and/or SOPs for recording data (*field and laboratory*), including guidelines for recording (manually, legibly in ink, initiated and dated by responsible person) and correcting data (e.g., single line drawn through errors, initiated and dated by the responsible person). The format of all data reporting should be consistent with the requirements and procedures used for data validation and data assessment described in Sections B, C, and D of the QAPP. The frequency and the contents of the management audits and QA reports should be identified in QAPP.

The following at minimum must be included in the laboratories data package:

- case narrative
- calibration (initial/continuing) summary and raw data
- mass spectrometer tuning data (if appropriate)
- gas chromatogram (if appropriate)
- mass spectra (if appropriate)
- quality control summary forms and raw data
- ICP, AA and graphite furnace data outputs (if appropriate)
- interelement correction data (if appropriate)
- blank data results
- method and instrumental detection limit results

C. Data Reporting Package Archiving and Retrieval

This element of the QAPP should identify the governing authority for storage of, access to, and final disposal of all records. The length of storage for the data reporting package may be governed by regulatory requirements, organizational policy, or contractual project requirements.

GROUP B: DATA GENERATION AND ACQUISITION

This element group describes the design and implementation of all measurement systems that will be used during the project. All sampling procedures, analytical methods/procedures, and data handling and documentation procedures are described completely. If standard operating procedures (SOPs) exist, then they are referenced and included as attachments to the QAPP. All quality control procedures, frequency requirements, acceptance criteria and corrective action procedures associated with the methods/procedures are documented for each phase of data collecting/generation.

The following QAPP sections should provide sufficient documentation to assure the reviewer that a representative sample of an appropriate matrix will be properly and consistently collected at the appropriate locations and that preventive and corrective action plans are in place prior to initiation of the sampling event.

INSTRUCTIONS for SAMPLING PROCESS DESIGN ***Element B1***

This element of the QAPP describes the sampling system in terms of what media/matrices will be sampled, where the samples will be taken, the number of samples to be taken and sampling frequency. The level of detail should be sufficient that a person knowledgeable in this area could understand how and why the samples will be collected. This element provides the main opportunity for QAPP reviewers to ensure that the “right” samples will be collected. Strategies such as stratification, compositing, and clustering should be discussed, and diagrams or maps showing sampling points should be provided. Most of this information should be available as outputs from the final steps of the planning (DQO) process.

Whether the QAPP describes an initial site investigation, a large scale remedial investigation/ feasibility study, a long-term treatment monitoring program, or voluntary monitoring program, the rationale for sampling specific points or locations must be explained in the QAPP.

- A. *The schedule of the project*** activities including the start and finished dates for: sampling events; analytical services by offsite laboratories; phases of sequential sampling (or testing), if applicable; trial run. Peer review activities should be provided in this section. This information could be referenced from Element A6, if all of these are included in that element.
- B. *The sampling design rationale*** for the collection of the data derived from quantitative outputs of the DQO Process (see Element A7A). For each medium/matrix, provide a detailed justification for the sampling design selected for the project. Describe the logic used to determine sample locations, analytical parameters and concentration levels and types, number and frequency of field samples and field QC samples to be collected. Describe or reference from other project documents the following information pertaining to the sampling plan selection:

- If a grid system will be used to select random sampling locations, then describe the basis for selecting the size of the grid and the number of sampling points per unit area. Note, if the grid system is to be used for long-term monitoring or a high degree of accuracy is required, the use of a certified land surveyor or a sensitive global positioning system should be considered. Also, note that simple random sampling is used primarily when the variability of a medium is known to be relatively small, i.e., the medium is homogeneous.
- If biota will be sampled, then describe the rationale for species and seasonal selection.
- If surface water samples will be collected, then describe the rationale for location selection.
- If field analytical measurements and/or screening techniques will be used to identify sample locations, then provide decision trees that document the critical decision points of the selection process.
- If samples will be composited, then provide the rationale and procedure for compositing.
- If a biased sampling approach will be used to select sampling locations, then describe the rationale for choosing a non-statistical approach.
- If biased/judgmental sampling will be performed, then describe the criteria for selecting “hot spots.”

Sampling location maps should be provided/referenced in this section. Site maps should include all well borings and test pit installations from previous investigations; buildings, etc., and must identify all areas with known or suspected toxic substance releases.

Provide Sampling location, Sampling and Analysis Method/SOP Requirements Tables.

INSTRUCTIONS for SAMPLING METHODS REQUIREMENTS **Element B2**

This element of the QAPP describes how samples will be collected. The selected sampling procedures must be appropriate to ensure that representative samples are collected in a consistent manner by project personnel; contamination is not introduced during collection; and all required sample media/matrices, locations and properly preserved volumes are collected to meet project objectives.

- A. *Sampling SOPs*** - All sampling procedures that will be used in the project must be documented in the QAPP to allow for review and approval. Standardized sampling procedures provide consistency between samplers; facilitate collection of accurate, precise and representative samples; and help to ensure data comparability and usability. The most efficient and cost-effective way to document project-specific sampling techniques is to include sampling SOPs as attachments to the QAPP.

SOPs should be written and formatted in accordance with EPA Guidance for the preparation of Standard Operating Procedures (SOPs) for Quality-Related Documents, (EPA QA/G-6). **In addition to a detailed step-by-step description of the sampling procedures, all SOPs must specify acceptable limits of performance and required corrective actions.**

Include SOPs for sampling each medium or matrix, for each analytical parameter, by each type of equipment and technique. Those SOPs must detail the appropriate number, size and type of sample containers to be used for collection of each field sample and field QC sample and chemical preservation procedures for those samples.

Include SOPs for any planned contingency actions that require additional and/or alternate procedures.

Provide a detailed description, explanation, and SOP for the use of all new and/or innovative sampling techniques that will be employed during the project. Provide documentation of the procedures as well as performance data and criteria to support the use of new/innovative techniques.

The attachment with project sampling SOPs should include a list of all SOPs.

- B. *Cleaning and Decontamination of Equipment/Sample Containers.*** This section of the QAPP should detail both the procedures for initial cleaning of sampling equipment and decontamination procedures that will be followed during the sampling event. These procedures help to ensure that collected samples are representative of the sampling location by verifying that sampling equipment are clean and free of contaminants of concern, other target compounds, and/or interferences. Cleaning/decontamination procedures must cover all equipment that contacts a sample.

Equipment Cleaning SOPs should be included as attachments to the QAPP. These SOPs should address the following: how equipment will be cleaned initially prior to field activities; frequency at which equipment will undergo full cleaning protocols; criteria for measuring cleanliness. If pre-cleaned bottles are used, then the QAPP should identify the vendor and describe where the certificates of cleanliness will be maintained.

Equipment Decontamination SOPs should be included as attachment to the QAPP. Decontamination procedure for each type of equipment should address: how equipment will be decontaminated in the field; frequency at which equipment will be decontaminated; criteria for measuring the effectiveness of the decontamination procedures; disposal of decontamination by-products, if applicable.

- C. *Field Equipment Maintenance, Testing and Inspection Requirements.*** This section of the QAPP should describe the procedures and documentation activities that will be performed to ensure that field and sampling equipment are available and in working order when needed. Equipment maintenance logs must be kept and equipment must be checked prior to use. Describe the records that will be kept to document field equipment maintenance, testing and inspection activities. Discuss the availability of spare parts and/or equipment to ensure that project schedules are met. Use Table 6 of Attachment A as an example for a list of critical spare parts. Specify how soon spare parts will be obtained and how soon equipment will be repaired.

- D. *Inspection and Acceptance Requirements for Supplies/Sample Containers.*** This section documents the procedures and activities that will be performed to ensure that all sampling supplies and sample containers are free of contaminants of concern, other target compounds, and interferences.

Itemize the supplies and sample containers that will be used when performing field activities including sampling activities. Identify all vendors for supplies and sample containers.

Describe the procedures that will be used to ensure adequate supplies and sample containers are on hand, and sample containers are traceable and clean. Discuss procedures for tracking, storing, and recording supplies and lot numbers for sample containers, as well as procedures for verifying container cleanliness, such as bottle blank analysis. Document the frequency for inspection activities, acceptable criteria, and the corrective action procedures employed to prevent the use of unacceptable supplies and/or sample containers. Identify the personnel responsible, by job function and organizational affiliation, for checking supplies, sample containers, and sample containers certificates of cleanliness, and the personnel responsible for implementing the corrective action. The required information may be presented in table format. If this information is contained in a SOP, then cite the SOP reference and include as an attachment to the QAPP.

For guidance on container cleanliness criteria, refer to “EPA Specifications and Guidance for Contaminant-Free Sample Containers” December 1992.

INSTRUCTIONS for SAMPLE HANDLING AND CUSTODY REQUIREMENTS ***Element B3***

This element of the QAPP should describe all procedures necessary for insuring that:

- samples are collected, transferred, stored and analyzed by authorized personnel;
- sample integrity is maintained during all phases of sample handling and analyses; and
- an accurate written record is maintained of sample handling and treatment from the time of this collection through laboratory procedures to disposal.

- A. *Sample handling.*** Proper field sampling documentation, and field analytical and laboratory documentation helps to ensure sample authenticity (i.e., the sample identity is correct) and data integrity.

The order of analytical parameter sample fraction collection (i.e., “volatile first, followed by extractable organics...”) for each matrix should be identified in this element of the QAPP.

Describe the sample numbering system for field sample collection and provide an example. If applicable, the numbering system should follow specific programmatic requirements that apply to the project. Use a systematic approach for numbering samples so that each

sampling location, medium/matrix, type, sample depth or height, and the date/time of collection can be uniquely identified and cross-referenced to the programmatic sample number, if applicable. The site-specific sample number should consist of the following:

- * Project Identification Code: A two-letter designation should be used to identify the site where the sample was collected. For example, the project identification code for the South Loop site will be 'SL'.
- * Sample Matrix and Location Code: Each sample should be identified by an alpha-code corresponding to the sample matrix/type, followed by a three-digit sample location number. The alpha-code as follows:

GW - Groundwater, monitoring well sample	SW - Surface water sample
SD - Sediment sample	SS - Surface soil sample
SB - Subsurface soil sample	TB - Trip blank sample
FB - Field blank sample	FD - Field duplicate sample

The location code will follow the sample type code. The location code consists of a two-to five-digit numeric or alpha-numeric code that indicates the sample location. Location codes lower than 10 will be preceded by '0', e.g., 01; 02; etc. For groundwater samples, the location code will be monitoring well number. Surface water samples, sediment samples, field blanks, and trip blanks will use a consecutive numbering system starting at 01.

- * Examples of Sample numbers: (1) SL-GWMW13 = South Loop site, groundwater sample from monitoring well MW13; (2) SL-GWMD13 = South Loop site, duplicate groundwater sample from monitoring well MW13; (3) SL-SW03 = South Loop site, surface water from location number 3

Define how samples will be batched or grouped to be sent to the laboratory. It is recommended that samples be grouped in Sample Delivery Groups (SDG). An SDG is defined as a group of twenty or fewer samples within the project, received by a laboratory over a period of up to fourteen calendar days or as defined by the contract. All QC samples (equipment blank, VOA trip blank, etc.) are counted as field samples in the sample SDG total.

Describe how samples will be delivered or shipped to the laboratory. Include the name of the carrier service, if applicable. Samples should be transported to the laboratory within twenty-four hours of sample collection, or shipped by an overnight delivery service (with coolers under custody seals) within twenty-four hours of sample collection. A major exception to this requirement is when published analytical holding times are less than twenty-four hours from sample collection. If alternative shipment schedules will be used, then describe those alternate time frames and provide rationale for their use. Shipment papers, including bills of lading and air bills, must be retained by the laboratory with Chain of Custody (COC) records.

Include examples of all sample shipment forms to be used.

Sample container, volume, preservation and holding time table. Document the required sample volumes, container types, number of containers, preservation procedures (chemical, temperature) and holding time for each analytical parameter, matrix and concentration level in a table. This table can be separate or, if appropriate, combined with the Sampling Locations and Analysis Method SOPs Requirements Table. Table 7 of Attachment A can be used as an example.

- B. *Sample custody.*** A sample is under custody if it is in someone's possession; if it is within someone's view; if it is in a locked, secured area after being in someone's possession, etc. COC is defined as the sequence of persons who have the item in custody. COC will be demonstrated by documenting that the item in question was always in a state of custody. This will be accomplished through a combination of field and laboratory records that demonstrate possession and transfer of custody.

The list of the names and responsibilities of all sample custodians in the field and laboratory should be included in this element.

This element will provide detailed procedures for chain of custody for field activities, laboratory activities, and final evidence files as follows:

1. Field Custody Procedures

- All sampling organizations must have and include in the QAPP detailed custody procedures that will be used for evidence collected in the field. All documents, logbooks, photographs, measurements, analyses, samples collected, etc. must be addressed in the field custody procedures. Detailed explanations will include:
 - * Procedures for transfer of custody between individuals.
 - * A sample numbering system (if not presented in another QAPP element).
 - * Sample packaging and shipment procedures to an off site laboratory.
- All entries will be completed with a permanent ink pen with no erasures or whiteout used. All entries will be signed/dated. Any entry which is to be deleted will use a single crossout which is signed/dated.
- Chronological sequences and instructions for completing all field custody documents as well as copies of each document (as applicable):
 - a. Field logbooks: The field logbook entry will provide all information pertinent to the collection of field samples including locations, number/types of samples, measurements, sampling/atmospheric conditions, observations, etc. The field

logbook will be a bound volume assigned to an individual field team member.

- b. Sample tags: A sample tag is attached to each individual sample aliquot for each investigative or quality control sample. At a minimum, the tag will include the field sample number, location (if not already encoded in the sample number), date/time of collection and type of analysis. A space for lab sample number (provided by the lab upon log-in) is also required.

A sample tag may be attached to the sample container with a wire around the container neck through a reinforced hole in the tag. All tag entries are made with a waterproof, permanent ink.

We strongly recommend use of **labels** (described below) in addition to tags. **Tags must always be used whenever chain of custody is required (*for enforcement purposes*)!** The sample tag is the only physical evidence of the sample aliquot as carried through the entire custody process outside of keeping all sample containers. Sample labels cannot usually be removed intact and often do not include enough space for information on smaller containers. Sample tags allow for disposal of sample containers once the samples have exceeded their holding times.

- c. Sample labels: As noted above, sample labels are strongly recommended when chain-of-custody is required. Sample labels may repeat some of the information provided on tags but usually cannot be removed intact. The use of labels minimizes the possibilities that sample containers and/or tags can be switched.
- d. COC record form: A COC record form is the form used to record information pertinent to all samples being shipped in the same cooler. In general, the form will record samples which may be shipped together (i.e., extractable organics or metals) to the same laboratory. The form will also include spaces for transfers of custody by the field team as well as for log-in by the lab sample custodian.
- e. Shipping cooler custody seals: Shipping cooler custody seals are placed on the edges of the cooler between the lid and sides to determine whether coolers may have been tampered with. The custody record form, along with all associated samples/tags, preservative (i.e., ice) and packing material are placed in the cooler prior to sealing with one or more seals.
- f. Air bills: Air bills used by the shipping company are often overlooked in the custody chain. Air bills are the only means to document and ensure continuity in custody between the shipment of samples from the field until their arrival at the laboratory. Copies of all completed air bills must be included as part of the final custody documentation.

2. Laboratory Custody Procedures

Detailed laboratory custody procedures specific to each laboratory associated with the project will be stated. The facility and its field contractor must ensure continuity between field and lab custody procedures. Laboratory custody procedures will:

- Begin when samples are received by the laboratory.
- Maintain the chain of custody initiated in the field.
- Provide the chronological sequence from sample log-in through sample analysis and disposal.
- Provide detailed log-in procedures.
- Detail the internal sample tracking and numbering systems.
- Identify the sample custodian.
- Detail transfers of custody within the laboratory.
- Provide examples of internal custody documents (with instructions for completion).
- Specify how and where samples are stored.
- Specify how and when samples, extracts, and digestates are disposed.
- Specify how custody of analytical data is maintained.
- Specify how analytical data and custody records are "purged" from the custody of the lab to the final evidence file.

3. Final Evidence Files: This section will specify:

- The contents of the final evidence file.
- The identification of the file custodian.
- The location where the file will be maintained in a secure, limited access area.
- The length of time (as mandated by U.S. EPA) that the file will be maintained. This may be specified in an order, etc. The file must be offered to U.S. EPA prior to disposal.

INSTRUCTIONS for ANALYTICAL METHODS REQUIREMENTS
Element B4

The following element of the QAPP includes all components of the project-specific analytical measurement system, including field and fixed laboratory analytical methods and SOPs.

This element of the QAPP should provide sufficient documentation to assure the reviewer that accurate and usable data will be generated and that preventative and corrective action plans are in place prior to initiation of the sampling event.

All contracted and/or subcontracted field analytical and fixed laboratory services must be in place in order for the final QAPP to be approved.

This section will describe the field, onsite mobile laboratory and fixed laboratory analytical procedures to be used for the site investigation. This section should document field analytical methods and SOPs and fixed laboratory analytical methods and SOPs that will be used to meet

measurement performance criteria and achieve project-required quantitation limits for contaminants of concern and other target compounds at the concentration levels and specific media/matrixes as identified in Element A6 of the QAPP. **Note the difference between methods and analytical SOPs: methods describe preparatory and analytical/determinative techniques used in target analyte identification and quantitation, while analytical SOPs document how a particular laboratory will perform a specific analytical method.**

The following information will be stated in this section:

- A. The analytical parameters and matrices to be tested will be stated for each laboratory involved in the project. Each laboratory address will be stated in this section of the QAPP. A reference to the specific section in the QAPP (Lab Responsibilities) is acceptable to satisfy this requirement.
- B. SOPs for sample preparation (i.e., extraction, concentration, etc., for organics; digestion, dilutions, etc., for inorganics) and cleanup methods, for all types of matrices will be listed/identified in this section of the QAPP. The preparation SOPs should be provided along with the analytical SOPs in the QAPP and will be referenced as an attachment in the document.
- C. SOPs for all analyses that will be performed on the samples collected from the site under investigation will be provided. The SOPs may be based on SW-846, or other EPA methods, such as those promulgated under the Clean Water Act (e.g., EPA 600 Series Organic Methods) and Safe Drinking Water Act (e.g., EPA 500 Series Methods) provided that the methods are sufficient to meet any defined project objectives. Some SOPs for inorganic analysis will be based on EPA-600/4-79-020 Methods for Chemical Analysis of Water and Wastes. The SOPs must be detailed and specify analytes and matrices of interest for this investigation. Pertinent sections of the equivalent SW-846 method may be referenced in the SOP, but need not be included if these sections are followed without modification. If any referenced sections offer several options, the option selected must be clearly stated.
- D. An explanation of how the method validation study (including detection limit study) was conducted. This should be based on the laboratory SOPs and must include the criteria for acceptance, rejection or qualification of data.
- E. Summary tables of analyte groups of interest (e.g., volatiles, acid/base/neutrals, metals, nutrients, etc.), including the appropriate laboratory SOP numbers and EPA method reference will be included in this section. For each analyte group on a matrix-specific basis, all the applicable sample preparation, cleanup and analysis SOPs will be included in a table format. In addition, list each of the project target compounds in each analyte group that will be measured and reported.
- E. The quantities and types of QC samples to be taken for each analyte group, on a matrix-specific basis will be included in this section. The DQO process should be used to define

the types and frequencies of analyzed QC samples. This list will reflect the specific needs of the project. The laboratory SOP will have a QC section which addresses minimum QC requirements. However, any additional project requirements will be addressed. (NOTE: Pertinent sections of the QAPP may be referenced.)

Analytical SOPs for field and fixed laboratories should be written and formatted in accordance with Guidance for Preparation of Standard Operating Procedures for Quality-Related Documents, (EPA QA/G-6). **In addition to a detailed step by step description of the procedure, all SOPs must specify appropriate QA checks and samples with explicit concentration and frequency requirements for preparation and analysis, QC acceptance limits and required corrective actions for each step of the procedure. The DQO process should clearly define these requirements.**

The following elements must be included in the analytical SOP:

- Parameters to be measured.
- Range of Measurement. Working Linear Range.
- Limits of Detection. Where appropriate, the procedure used for determination of method detection limits will be specified.
- Sample Matrix.
- Principle, Scope and Application.
- Interferences and Corrective Actions. Specify method/steps to be taken to eliminate the interference. Method will be matrix-specific.
- Safety Precautions.
- Sample Size, Collection, Preservation, and Handling. Describing for each matrix which measurement procedure is applicable.
- Apparatus, including instrument and instrumental parameters and materials.
- Routine Preventive Maintenance, including procedures and frequency.
- Reagent and Calibration Standards, including preparation procedures, storage and shelf life.
- Calibration Procedures, including instrument tuning and routine performance checks, etc. If appropriate, specify whether internal standard or external standard techniques are to be used.
- Procedures for Sample Preparation (i.e., extraction, digestion, etc.).
- Analytical Measurement. Describe in cookbook detail. Include separate details for each sample matrix if the procedure is applicable to more than one sample matrix.
- Flow Chart or Table that describes the method step by step.
- Data Treatment. Details of calculations, including equations.
- Data Deliverables (define the content of data packages), as a minimum, the following will be provided:
 1. Case narrative, briefly describe the sample preparation and analysis, problems encountered and corrective action taken during the process of sample preparation and analysis.
 2. Summary of initial calibration and continuing calibration check results.

3. Summary of sample analysis, arranging in increasing order of sample number.
 4. Summary of QC sample analyses.
 5. Raw data including instrument printouts, mass spectra, chromatograms, etc.
- Quality Control Requirements. Specify internal requirements for blanks, spikes, duplicates and external requirements for reference and QC samples.
 - References.
 - Method Validation Data (if available) should be included to support the validity, limitation and applicability of the measurement method.

Provide a detailed description, explanation and SOP for use of all new and/or innovative analytical techniques that will be employed during the project. Provide documentation of the procedures as well as method performance data and criteria to support the use of new/innovative techniques.

NOTE: The SOPs and method validation study will be submitted along with the QAPP and will be referenced as an attachment in the document.

INSTRUCTIONS for QUALITY CONTROL REQUIREMENTS
Element B5

Quality Control (QC) is the overall system of technical activities which measure the attributes and performance of a process, item, or services against defined standards to verify that they meet the stated requirements established by the customer. Different QC checks and samples are used to both prevent and identify specific sources of error in a particular project activity or part of the process. Acceptable limits of performance must be defined quantitatively and/or qualitatively and documented in SOPs and summarized in tables for each QC check and sample used in the project. These laboratory-specific QC acceptance limits must support the measurement performance criteria that were determined during the systematic planning process. In turn, project data validation criteria should support both laboratory-specific QC acceptance limits and the project required measurement performance criteria.

A. Field Sampling Quality Control

This section of the QAPP identifies the QC procedures, checks, samples, and their respective acceptance limits, that will be used during the project to monitor the quality of various aspects of the sampling event(s). Their required analysis frequency, acceptance limits and corrective actions are also documented in this section of the QAPP. Types of Field QC samples are listed below and include, but are not limited to:

- Replicate measurements per sample (if applicable).
- Duplicate samples.
- Reference standards (used in calibrating field instruments such as pH meters, specific conductance or conductivity meters, potentiometer for Eh measurements, HNU GC for organics, etc.).
- For temperature measurements, comparison of the thermometer with an NIST traceable

thermometer.

- Reference standards for turbidity measurements (Nephelometric method, etc.).
- Munsell color chart for color checks.

If SOP QC acceptance limits exceed the project specific measurement performance criteria, identified in Element A7B, then the data obtained maybe unusable in making project decisions.

B. Analytical Quality Control Checks

This section of the QAPP identifies the QC procedures, checks, samples, and their respective acceptance limits, that will be used during the project to monitor the quality of various preparatory and analytical steps. EPA methods generally provide QC acceptance limits for most of the QC checks and samples required by those methods. Certain EPA methods (and other non-EPA methods) require that laboratories generate their own specific QC acceptance limits for some of the QC checks and samples required by those methods. These method and/or laboratory-specific limits, however, may not be “tight” enough to support the project quality objectives. In other words, QC sample or check results may meet method/SOP QC acceptance limits but fail to meet the project measurement performance criteria as defined and documented in Element A7B. Therefore, it is important to select methods having QC acceptance limits that support the collection of usable project data. Subsequently, it is critical to choose a laboratory that is capable of meeting the project-required QC acceptance limits.

For some projects, the selected EPA method or non-EPA method may not have sufficient QC checks and samples built into the method. In these cases, the Project Team will need to specify what additional QC checks and samples must be analyzed by the laboratory. The laboratory should document additional project-required QC in its analytical SOPs along with the required frequency, acceptance criteria and corrective actions for those QC checks and samples. Types of Analytical QC samples are listed below and include, but are not limited to:

- Field/Trip Blanks.
- Method Blanks.
- Reagent/Preparation Blanks (applicable to inorganic analysis).
- Instrument Blanks.
- Initial Calibration.
- Continuing Calibration and/or Calibration Verification Check.
- Matrix Spikes/Matrix Spike Duplicates.
- Surrogate Spikes.
- Analytical Spikes (Graphite furnace).
- Field Duplicates.
- Laboratory Duplicates.
- Laboratory Control Standards.
- Internal standard areas for GC/MS analysis; control limits.
- Mass tuning for GC/MS analysis.
- Endrin/DDT degradation checks for GC/EC analysis.

- Second, dissimilar column confirmation for GC/EC analysis.

If analytical parameters have multiple analytes, then provide precision and accuracy for each analyte.

If SOP QC acceptance limits exceed the project specific measurement performance criteria identified in Element A7B, then the data obtained maybe unusable in making project decisions.

INSTRUCTIONS for INSTRUMENT/EQUIPMENT TESTING, INSPECTION, and
MAINTENANCE REQUIREMENTS
Element B6

The purpose of this element of the QAPP is to discuss the procedures used to verify that all instruments and equipment are maintained in sound operating condition and in working order when needed.

Instrument/equipment maintenance logs must be kept and equipment must be checked prior to use. Describe the records that will be kept to document instrumentation maintenance, testing and inspection activities for both field and laboratory instruments.

A. Field Instrument Maintenance

Maintenance procedures for equipment such as thermometers, pH and conductivity meters will be addressed. The use of photoionization detectors and organic vapor analyzer systems will be addressed in this Section of the QAPP unless used only for health and safety purposes. It will be indicated how frequently such instruments will be checked (possibly as part of daily calibrations), and where and how frequently such checks will be documented. Lists of critical spare parts such as tape, pH probes and batteries should be presented in the QAPP, in tabular format (this table can be included in an attachment/appendix). Any other means for ensuring that equipment to be used in the field is routinely serviced, maintained or repaired will be stated. Use Table 6 of Attachment A as an example.

B. Laboratory Instrument Maintenance

These procedures are designed to minimize the occurrence of instrument failure and other system malfunctions and will also be included in this section of the QAPP. The laboratory's (ies') schedule for maintenance of each instrument to be used during implementation of the project will be presented in tabular format. A list of critical spare parts necessary for maintaining this equipment will also be presented in tabular format. Although it is understood that laboratory instruments are usually maintained in accordance with manufacturers' specifications, it is not acceptable to submit copies of instrument manuals to satisfy the intent of this element. If preventative maintenance is performed through a vendor contract, this information will be stated. Use Table 8 of Attachment A as an example.

INSTRUCTIONS for INSTRUMENT CALIBRATION and FREQUENCY
Element B7

To ensure that the analytical methods and selected instrumentation meets the project requirement for selective, sensitive and precise detection and quantitation of the analytes of interest, it is necessary to completely describe the calibration procedures for each *field* and *laboratory* analytical instrument. This section of the QAPP demonstrates the ability of the *field* and *laboratory* analytical technique to accurately and precisely identify and quantitate the contaminants of concern and other target compounds at the required quantitation limits and within the required measurement ranges.

Calibration procedures may be documented separately in this section of the QAPP or included in the appropriate analytical SOPs as attachments to the QAPP. In either case, the following items, where appropriate, must be addressed for each analytical procedure:

- Frequency of initial and continuing calibration.
- Number of calibration points, calibration levels for multipoint curves, and calibration standards at the required quantitation limit concentration for each contaminant of concern and other target compounds.
- Linearity calculation techniques.
- Acceptance criteria for calibration.
- Calibration level for calibration verification standards. In order to assess instrument drift, a calibration verification standard should be run periodically during the analytical sequence and at the end of the analytical sequence.
- Corrective action for non-conformance.
- Calibration/Standard Documentation: Describe what documentation will be generated for calibration and standards for each instrument.
- Standard Traceability: Describe the procedures to be used to assure standard traceability. Standards must be traceable to a verifiable source such as NIST standard. Standards may be purchased as ampulated mixtures with certificates of analysis, however, it is the laboratory's responsibility to ensure the accuracy of the standard solutions.
- Second Source Verification: Describe the use of second source verification standards. Even certified standards may change over time or not meet vendors' specifications. A relatively inexpensive way to verify the analytes and concentration of standard is to analyze a standard containing the same analytes from another vendor. By applying routine comparability criteria, greater assurance is gained in the identification and quantitation of target analytes in an analytical sample. The data from two standards can be compared, using previously established comparability criteria to assess accuracy.

INSTRUCTIONS for INSPECTION/ACCEPTANCE REQUIREMENTS
for SUPPLIES and CONSUMABLES
Element B8

This element of the QAPP documents procedures and activities that will be performed to ensure that all supplies used in the field and laboratory will be available when needed and will be free of

contaminants of concern, other target compounds and interferences.

Itemize the supplies that will be used when performing *field* or *laboratory* work. Identify all vendors for supplies and reagents.

Describe the procedures that will be used to ensure supply cleanliness and reagent purity. Discuss procedures for recording reagent lot numbers for measuring supply cleanliness. Document corrective action procedures employed to prevent the use of unacceptable supplies. Identify the person(s) responsible for checking supplies and implementing corrective actions. If this information is contained in an SOP, then cite the SOP reference. Alternatively, the required information may be presented in a table.

INSTRUCTIONS for DATA ACQUISITION REQUIREMENTS
(NON-DIRECT MEASUREMENTS)
Element B9

This element of the QAPP should clearly identify the sources of previously collected data and other information that will be used to make project decisions. It is essential to identify the limitations on the use of acquired data, since using data and information that are not generated under the same quality objectives as the current investigation may result in erroneous decisions.

Acquired data are defined as information from any source outside of the current activity that may impact the environmental decision making process. Secondary sources of acquired data and information include, but are not limited to:

- Historical data (e.g., from organization's/facility's corporate records and/or federal/state local records pertaining to previous monitoring events, site assessments, investigations, etc.). Historical data may have been used in Element A5 to describe the site history and define the environmental problem.
- Background information/data from organization's/facility's corporate records and/or federal/state/local records pertaining to site specific industrial processes, process by-products, past and current chemical uses, raw material and finished product testing, waste testing and disposal practices, and potential chemical breakdown products.
- Data generated to verify innovative technologies and methods.
- Data generated from computer databases (such as manufacturers' process/product information, waste management or effluent information).
- Environmental indicator data obtained from federal/state/local records.
- Computer models or algorithms.
- Literature files/searches.
- Publications.
- Photographs.
- Topographical Maps.

Note that the quality of acquired data will become an increasingly important issue for many EPA programs, e.g., Brownfields initiative. To ensure that correct environmental decisions are made,

the same care should be taken using secondary data as is taken in generating new data.

A table with all non-direct measurements data/information that will be used for this project and their originating sources will be appropriate. Specify how those acquired data/information will be used and the limitations on their use.

Discuss in the text the quality of all non-direct measurement data as well as the completeness of the data documentation. Identify the generator(s) of the data, dates the data were generated/collected and reported, sources from which the data were obtained and procedures originally used to generate and collect the data (including sampling, analytical, and assessment procedures). If known, describe all QC procedures, checks and samples that were analyzed with the data set. Describe the method and/or laboratory-specific QC acceptance criteria used for data generation and whether or not data were verified and/or validated. If data were verified and/or validated, then describe the criteria and procedures used, the documentation provided, as well as, the results obtained from previous verification and/or validation activities.

Discuss in the text, the quality of previously generated data, addressing the following issues:

- If the data were generated under an approved QAPP or other sampling document, reference the document by title, date, originating organization, and approving organization.
- Evaluate the purpose and scope of previous studies and compare with current study objectives. Evaluate similarities and differences of the measurement performance criteria and data quality indicators.
- Evaluate the design and implementation of the previous study by examining the following issues:
 - a. Whether the study was conducted properly.
 - b. Whether control responses were within acceptable limits.
 - c. Whether standard sampling and analytical methods and/or standard QA/QC protocols were available and followed by the study.
- Include a brief description of the sampling procedures per matrix type and analytical procedures per matrix type.
- If performance and/or system audits and/or split sampling activities were performed, then provide the results of those audits/activities.
- If data were verified and/or validated, reference the verification and/or validation procedure by title, date, and originating organization.
- If data are obtained from a computer model/algorithm, then provide a brief description of the validation of the software.
- If data are obtained from a database, then provide a brief discussion on the integrity/accuracy of the database information.
- Discuss the adequacy of the original QA documentation under which secondary data were generated. For example, if insufficient raw analytical data are available to verify that an instrument was calibrated accurately, then the secondary data may be not usable for their intended purpose.

Discuss all possible limitations on the use of previously generated/collected non-direct measurement data for this project based upon the uncertainty surrounding their quality. Discuss the nature and magnitude of that uncertainty. For example, discuss the impact of using unvalidated historical monitoring data to answer project questions and support project decisions. Unvalidated data may be scientifically inaccurate or may not meet the objectives of the user. Also, discuss the impact of using acquired data with known analytical or sampling inaccuracy/ bias and/or imprecision. For example, document the sampling and analytical methods used to collect and analyze soil VOA samples and discuss possible low bias in sample results.

Document the acceptance criteria used to determine whether those previously generated/ collected non-direct measurement data/information are usable for this project. For example, if acquired drinking water data will be used to answer project questions, then the QAPP should state that only data generated by EPA/State certified laboratories will be used for this project. Provide comparability criteria for previously generated/collected non-direct measurement data (e.g., historical routine monitoring data) and data generated for this project.

INSTRUCTIONS for DATA MANAGEMENT ***Element B10***

This element should present an overview of all computerized and manual procedures performed on all data from generation to final use and storage. A diagram that illustrates the source(s) of the data, the processing steps, the intermediate and final data files, and the reports produced maybe helpful. Include applicable SOPs as attachments to the QAPP. Also describe the associated quality checks for error detection that are performed to ensure data integrity. The following data management steps should be addressed:

A. Data Recording

- Provide examples of data entry forms.
- Describe internal checks to detect errors in data entry process, i.e., transcription and calculation errors, etc.
- Identify personnel responsible for identifying and correcting recording errors.
- Provide examples of all verification checklists/forms.

B. Data Validation

The details of the process of data validation and prespecified criteria should be documented in this element of the QAPP. The element should address the following:

- Data validation procedures will be performed for both field and laboratory operations.
- Sampling and analysis procedures must be complete to prepare and review a validation procedure.

- Validation procedure must specify the verification process of every quality control measure used in the field and laboratory.
- A validation procedure in the form of the SOP should be prepared for each analytical procedure and submitted for review as an attachment.
- The U.S. EPA National Functional Guidelines for Organic and Inorganic Data Review are only directly applicable to Contract Laboratory Program Statements of Work (CLP-SOWs) low/medium analyses. For SW-846 and other analytical methods, this guidance document can be used to construct the validation procedures for these methods.
- All qualifiers used in the validation report as well as the contents of the validation report must be defined.
- As outlined in Element A9, a minimum data deliverables package documenting analyses is necessary for a complete validation of enforcement lead projects.

C. Data Transformation/Data Reduction

Data transformation is conversion of individual data point values into related values or possibly symbols using conversion formulas. The procedures for all data transformation/reduction should be described and recorded in this element. The QAPP should address the following:

- Provide the equation(s) used to calculate results, e.g., calculation of dry weight, etc. It may be acceptable to reference applicable section(s) of analytical SOPs where equations may be found.
- Describe when and how data conversion procedures are performed, how they are checked, and responsible personnel.
- Describe all data manipulations, applicable for each matrix to be analyzed, involved in reducing raw data to reportable data and responsible personnel.
- Provide an example of how raw data are reduced for all manual and automated calculations, e.g., calculations of sample concentrations from peak areas, etc.
- Provide references to specific software documentation for automated data processing.
- Describe internal checks to detect errors, the resultant documentation generated, and responsible personnel. Provide examples of all verification checklists/forms.

D. Data Transmittal/Transfer

Data transmittal occurs when data are transferred from one person or location to another or when data are copied from one form to another. The QAPP should address the following:

- Identify electronic data transfer software.
- Provide examples of electronic data transfer forms.
- Describe manual data transcription and electronic transmittal procedures, the resultant documentation generated, and responsible personnel.
- Describe internal checks to detect errors, the resultant documentation generated, and responsible personnel. Provide examples of all verification checklists/forms.

E. Data Analysis

This element should briefly outline the proposed methodology for data analysis and a more detailed discussion should be included in the final report. The QAPP should address the following:

- Identify and describe the data equipment and computer hardware and software that will be used to process, compile and analyze project data, e.g., the Laboratory Information Management System (LIMS), and acquired/secondary data as discussed in Element B9.
- Describe in detail, and/or include as attachments to the QAPP, the computer models and/or algorithms that will be used for data analysis and justify their use for this project.
- Identify hardware requirements (especially computer disk space, memory, and speed) that will be required to run and compile modeling data.
- Describe any specific performance requirements for the hardware/software configuration, model or algorithm.
- Describe computer test procedures and manual verification check procedures used to demonstrate acceptability of hardware/software configurations and computer programs and models, the resultant documentation generated, and personnel responsible. Provide example check data and examples of all verification checklists/forms.

F. Data Assessment

- Describe in detail, and/or include as attachments to the QAPP, statistical computer programs that will be used to assess data.
- Describe in detail, and/or include as attachment to the QAPP, the computer validation programs that will be used to validate the data.
- Identify hardware requirements (specifically computer disk space, memory, and speed) that will be required to run the validation and/or assessment software.
- Describe computer test procedures and manual verification check procedures used to demonstrate the acceptability of hardware/software configurations and computer programs, the resultant documentation generated, and personnel responsible. Provide examples of all verification checklists/forms.

G. Data Tracking

Describe in this element of the QAPP, or include as an attachment to the QAPP, procedures for tracking data as they are collected, transformed/reduced, transmitted and analyzed. The responsible personnel should be identified.

H. Data Storage and Retrieval

This element of the QAPP should discuss data storage and retrieval including security and length of retention. It should document the complete control system. The QAPP should address the following:

- Discuss, and/or include as attachments to the QAPP: data storage; archival and retrieval procedures for all project data; documents, records and reports. Differentiate between

hard copy and electronic data and information.

- Identify specific project data, documents, records, reports, etc. that will be stored and/or archived. Differentiate between hard copy and electronic data information. Differentiate between documentation stored at a subcontracted laboratory and documentation archived by the Lead Organization. If data package deliverables do not include all data documentation, then describe what data (for field screening, field analysis and fixed laboratory) will be kept by which laboratory or other organization, and provide the exact physical location, i.e., complete laboratory/organization name, address and specific location of the building.
- Identify the organizations and personnel that are responsible for storing/archiving/retrieving specific project documents. Identify the responsible document control personnel, including organization affiliation, telephone and telefax number.
- Describe where the documents will be stored during the project and where the documents will be archived. Provide exact location (organization name, complete address and specific location in the building) and time frames in which documents will be moved from one location to another.
- Indicate when documents will be archived to a final location.

I. Data Security

- Describe, and/or include as an attachment to the QAPP, procedures for data security.
- Describe, and/or include as an attachment to the QAPP, procedures for the computer security.

GROUP C: ASSESSMENT/ OVERSIGHT

This element details the procedures used to ensure proper implementation of the QAPP. This group of QAPP elements addresses the activities for assessing the effectiveness of the implementation of the project and the associated QA/QC activities.

This element should identify any deviations from the QAPP and describe the process by which the need for correction action is documented, reported, implemented and its effectiveness assessed.

INSTRUCTIONS for ASSESSMENT and RESPONSE ACTIONS ***Element C1***

This section of the QAPP identifies the number, frequency and type of planned assessment activities that will be performed for the project. Assessments should be conducted periodically throughout the project by entities internal and/or external to the project to ensure that usable data are generated. The internal audits will be performed by the organization primarily responsible for performing the task. The external audits will be performed by U.S. EPA. In addition, oversight assessments should be performed by the Approval Authority to identify and correct non-conformances so that project quality objectives can be achieved.

Although any external assessments that are planned should be described in the QAPP, the most important part of this element is documenting all planned internal assessments. Generally, internal assessments are initiated or performed by the internal QA Officer so the activities described in this element should be related to the responsibilities of QA officer as discussed in Element A4.

Appropriately scheduled assessments allow management to implement corrective action measures in a timely manner, thereby minimizing the impact of non-conformance on achieving project quality objectives. The project quality objectives dictate the type, frequency, and extent of the assessments which should be performed.

A. Planned Assessments

If no assessments are planned, then document this information and provide a justification in this element of the QAPP.

Many different types of assessments are available to evaluate the effectiveness of project activities. The following may be performed as internal or external assessments by the project participants or as oversight audits by EPA or the delegated Approval Authority.

- Field Sampling Technical System Audit (TSA) - This is an on-site audit during which sampling design, equipment, instrumentation, supplies, sampling procedures, COC, sampling handling and tracking, data reporting, data handling and management, data tracking and control, and data verification procedures are examined for conformance with the QAPP. It is recommended that at least one Field Sampling TSA be performed at the start of field sampling activities so that effective corrective action measures can be

implemented to mitigate the extent and impact of identified non-conformances.

- Field Analytical TSA - This is an audit of on site field analytical techniques (not performed in a mobile field laboratory) during which the equipment, instrumentation, supplies, personnel, training, analytical methods/procedures, sample handling and tracking, data reporting, data handling and management, data tracking and control, and data verification procedures are checked for conformance with the QAPP. A Field Analytical TSA can be performed prior to the start, at the start of, or at any time during field sampling activities. However, it is recommended that at least one Field Analytical TSA be performed prior to the start of the field sampling activities so that effective corrective action measures can be implemented to mitigate the extent and impact of identified non-conformances.
- Field and Fixed Laboratory TSA - This is an audit of an on-site field laboratory and fixed laboratory during which the facility, analytical instrumentation, supplies, personnel, training, analytical methods/procedures, laboratory procedures, sample handling and tracking, data reporting, data handling and management, data tracking and control, and data verification procedures are checked for conformance with QAPP. The field and fixed laboratories TSA can be performed prior to the start, at the start of, or at any time during field sampling activities. However, it is recommended that at least one Laboratory TSA be performed prior to the start of the field sampling activities so that effective corrective action measures can be implemented to mitigate the extent and impact of identified non-conformances.
- Performance Evaluation (PE) Sample Tracking and Analysis - Results from PE samples are statistically analyzed to provide information on routine laboratory performance and the overall accuracy and bias of the analytical method. “Blind” PE samples are those whose identity is unknown to those operating the measurement system. Blind PE samples often produce better performance assessments because they are handled routinely and are not given the special treatment that known PE samples sometimes receive. The QAPP must address the selection of appropriate PE samples. Factors to consider include but not limited to single or double blind, analyte selection, spiked or natively contaminated or both, multiple matrices and concentrations, total number of PE samples, and analytical methods.
- Data Validation TSA -This is a review of the complete Data Validation Report including a review of the associated analytical data package deliverables (tabulated and raw data) to ensure that all required analytical data package deliverables were provided and contain the specified information. The Data Validation TSA also ensures that the data validation procedures and action specified in the QAPP are utilized, the data validation criteria specified in the QAPP are met, and the method and laboratory specific QC acceptance criteria specified in the QAPP are met and were appropriate for achieving the project measurement performance criteria. The Data Validation TSA also evaluates whether the project-specific measurement performance criteria and data validation criteria were appropriate for meeting the specified DQOs and whether there were analytical measurement performance usability issues affecting DQO achievement.
- Data Package TSA - This type of Data Validation TSA is limited to a review of the

complete analytical data package deliverable generated by the field and/or fixed laboratory to ensure that all required deliverables are provided and contain all the information required to reproduce all reported results. The Data Package TSA also ensures that the data verification procedures specified in the QAPP are used by the laboratory producing the analytical data package deliverable. It ensures that the method-specific QC acceptance criteria specified in the QAPP are met and were appropriate for achieving the project measurement performance criteria.

- Management System Review (MSR) - This is a review of an organization or organizational subset to determine if the management structure, policies, and procedures are sufficient to ensure that an effective quality system is in place to support the generation of usable project data.

A table may be provided in the QAPP that includes the following: type of assessment; frequency; organization performing assessment; and staff responsible for performing these audits.

B. Assessment Findings and Corrective Action Responses

Describe how QAPP deviations and project deficiencies, which are identified through the planned project assessments, will be handled. Assessment findings that require corrective action initiate a sequence of events that include documentation of deficiencies, notification of findings, request for corrective action, implementation of corrective action, and follow-up assessment of the corrective action's effectiveness.

For each type of assessment:

- Describe how deficiencies will be documented and communicated (e.g., verbal debriefing after audit and/or written audit report, etc.).
- Describe what type of corrective action responses will be required and how corrective action responses will be documented.
- Identify who will be notified of the audit findings. Provide the name, title, organization affiliation, position, and telephone/telefax number of all individuals that must be notified of deficiencies/non-conformances.
- Identify to whom the corrective action responses will be directed and in what time frame.
- Include time frames allowed for the notification of audit findings, the request for corrective action, to perform the corrective action for each deficiency and the transmittal of corrective action responses.

The required information may be presented in tabular format.

The content and format of corrective action responses should be tailored to suit the project quality objectives. In certain situations, a letter documenting specific procedural changes may be a sufficient corrective action response. Appropriate procedural changes can include, but are not limited to: additional staff training; revisions of SOPs; and rescheduling of field and analytical activities (to ensure holding times are met, etc.). Corrective actions which require immediate implementation to ensure that project quality objectives are met may require work to cease until

those corrective actions are implemented and their effectiveness verified.

INSTRUCTIONS for REPORTS TO MANAGEMENT
Element C2

Planned QA Management Reports ensure that management and stakeholders are periodically updated on the project status and results of QA assessments. Efficient communication of project status and problems allows management to implement timely, effective corrective actions so that quality objectives can be met.

It is important that the QAPP identify the personnel responsible for preparing the report, evaluating their impact, and implementing follow-up action.

The QAPP should indicate the frequency and describe the content of Management Reports that will be generated for the project. Assessment checklists and reports, and requests for corrective action letters should be included as attachments to the QA Management Reports. Also, copies of all corrective action response letters and Corrective Action Forms should be included as attachments to the QA Management Reports.

All QA Management Reports must be included in the Final Project Report. If no QA Management Reports are generated for the project, then the QA/QC section which discusses the following issues must be included in the Final Project Report:

- Summary of project QA/QC programs and training conducted during the project.
- Conformance of project activities to QAPP requirements/procedures.
- Status of project and schedule delays.
- Deviations from the approved QAPP and approved amendments to the QAPP.
- Results and trends of PE samples by laboratory (by parameter, matrix and concentration level).
- Description and findings of TSAs and other assessments.
- Results of data validation activities in terms of amount of usable data generated.
- Required corrective actions and effectiveness of corrective action implementation.
- Data quality assessments in terms of precision, accuracy, representativeness, completeness, comparability, and sensitivity.
- Limitation of the use of measurement data generated.

The Final Project Report must meet project quality objectives and, at minimum, include:

- Development of Project Quality Objectives, Narrative and Time Line of Project Activities.
- Summary of Major/Critical Problems encountered and their resolutions.
- Data Summary including: tables, charts and graphs with appropriate sample identification/station location numbers, concentration units, percent solids (if applicable), and data quality flags.
- Reconciliation of project data with project quality objectives.
- Conclusions and recommendations.
- All QA Management Reports (as attachments to the Final Project Report document).

and/or QA/QC section that addresses the issues listed above.

GROUP D: DATA VERIFICATION/VALIDATION AND USABILITY

This element details the QA activities that will be performed to ensure that the collected data are scientifically defensible, properly documented, of known quality and meet project objectives. All analytical data collected for Region 5 must be validated. The type of ‘validation’ should be tailored to the specific project needs. In some cases, running the results through a standardized data assessment software application, such as CADRE, may be sufficient. CADRE uses the US EPA National Functional Guidelines for Data Validation as the basis for qualifying the results of CLP generated data, with some Region specific modifications. The validation guidance should be referenced/provided in the QAPP. After data have been validated, evaluating the impact of sampling error may assess data usability.

The following two steps are required to ensure that project data quality needs are met:

- A. *Data Verification/Validation*** - Data verification/validation consist of evaluating the completeness, correctness, and conformance or contractual compliance of a data set against the method standard, SOP, or contract requirements documented in the project QAPP. This activity should be performed internally by the analytical group or fixed laboratory generating the data. Additionally, data can be checked by an entity external to the analytical group or fixed laboratory. In addition, the qualification of data beyond method, procedural, or contractual compliance is done to determine the analytical quality of a specific data set. These criteria are based on measurement performance criteria developed in Element A7B of the project QAPP. Region 5 requires that these activity must be performed by an organization independent of the group that generates the data. At the conclusion of data verification/validation process, specific analytical results are identified as, useable without qualifications, qualified as estimated with a potential low or high bias; or rejected data (i.e., unuseable). Data verification may result in accepted, qualified or rejected data.
- B. *Data Usability Assessment*** - Data usability assessment is the process of evaluating verified/validated data to determine if they can be used for the purpose of the project, i.e., to answer the environmental questions or to make the environmental decision that must be made. Data usability includes the following sequence of evaluation:
- First, individual data sets are evaluated to identify the measurement performance/ usability issues/problems affecting the ultimate achievement of DQOs.
 - Second, an overall evaluation of all data generated for the project is performed.
 - Finally, the project-specific measurement performance criteria and data verification/validation criteria documented in the QAPP are evaluated to determine if they were appropriate for meeting project DQOs.

In order to perform either of the data evaluation steps above, it is necessary that reported data be supported by complete data packages (as itemized in Elements A9 and B10) which include sample receipt and tracking information, COC records, tabulated data summary forms and raw analytical data for all field samples, standards, QC checks and QC samples, and all other project specific

documents that are generated.

If relevant raw data and/or sample information documenting data quality are not available, then data verification/validation cannot be performed and only limited data review can be performed. This document defines reviews of data/information that do not have sufficient, documented QC as “limited data reviews” (LDRs). LDRs result in unquantifiable measurement error and unknown degree of uncertainty associated with the data. Those data are considered to be unknown and of undocumented quality. Ultimately, decisions that are made based on the data may be wrong. Data that is of unknown or undocumented quality should only be used in exceptional circumstances. Resampling or reanalysis must be considered first.

INSTRUCTIONS for DATA REVIEW, VALIDATION and VERIFICATION
REQUIREMENTS
Element D1

The purpose of this element is to describe the process for documenting the degree to which the collected data meet the project objectives, individually and collectively. Investigators should estimate the potential effect that each deviation from the QAPP may have on the usability of the associated data item, its contribution to the quality of reduced and analyzed data, and its effect on the decision.

Verification and validation procedures and criteria must be established prior to data validation. Specific project verification and validation criteria are developed to identify and qualify data that do not meet the measurement performance criteria as established in Element A7B. Data verification and validation criteria and procedures are documented in this element of the QAPP to ensure that data are evaluated properly, completely, and consistently for use in meeting the project quality objectives.

This element should state the criteria used to review and validate, i.e., accept, reject, or qualify, the data in an objective and consistent manner.

Examples of any forms or checklists to be used for data review, validation or verification should be provided.

Each of the following areas of discussion should be included in this QAPP element.

Document the procedures and criteria used to verify and validate data information operations. These operations include, but are not limited to: the electronic and/or manual transfer, entry, use and reporting of data for computer models and databases, and so forth.

- **Sampling Design** - How closely a measurement represents the actual environment at a given time and location is a complex issue that is considered during development of Element B1 of the QAPP. Each sample should be checked for compliance with the specifications, including type and location. By noting the deviation in sufficient detail, the data user will be able to determine the data usability under scenarios different from those included in project planning.

- Sample collection procedures - All expected deviations from Element B2 of the QAPP should be identified in this element. Acceptable departures (for example, alternate equipment) from the QAPP, and the action to be taken if the requirements cannot be satisfied, should be specified for each critical aspect. Comments from field surveillance on deviations from written sampling plans should be noted.
- Sample Handling - Deviations from the planned sample handling procedures described in Element B3 of the QAPP should be noted on the COC forms and in the field notebooks. Data collection activities should indicate the events that occur during sample handling that may affect the integrity of the samples. At a minimum, the investigators should evaluate the sample containers and the preservation methods used and ensure that they are appropriate to the nature of the sample and the type of data generated from the sample. Checks on the identity of the sample (e.g., proper labeling and COC records) should be made to ensure that the sample continues to be representative of its native environment as it moves through the analytical process.
- Analytical Procedures - Each sample should be verified to ensure that the procedures used to generate the data (as identified in Element B4 of the QAPP) were implemented as specified. Data validation activities should determine how seriously a sample deviated beyond the acceptance limit so that the potential effects of the deviation can be evaluated.
- Quality Control - Element B5 of the QAPP specifies the QC checks that are to be performed during sample collection, handling and analysis. For each specified QC check, the procedures, acceptance criteria and corrective action (and changes) should be specified. Data validation should document the corrective actions that were taken, which samples were affected, and the potential effect of the actions on the validity of the data.
- Calibration - Element B7 of the QAPP addresses the calibration of field and laboratory instruments and the information that should be presented to ensure that the calibrations:
 - * were performed within an acceptance time prior to generation of measurement data;
 - * were performed in the proper sequence;
 - * included the proper number of calibration points;
 - * were performed using standards that “bracketed” the range of reported measurement results (otherwise, results falling outside the calibration range are flagged as such); and
 - * had acceptable linearity checks and other checks to ensure that the measurement system was stable when the calibration was performed.

When calibration problems are identified, any data produced between the suspect calibration event and any subsequent recalibration should be flagged to alert data users.

- Data Reduction and Processing - Checks on data integrity evaluate the accuracy of raw data and include the comparison of important events and duplicate rekeying of data to

identify data entry errors.

INSTRUCTIONS for VALIDATION and VERIFICATION METHODS
Element D2

This element of the QAPP describes the process that will be followed to verify and validate the project data.

Describe how sample collection, handling, and field analysis procedures will be verified/ validated internally against the measurement performance criteria specified in Elements A7B and B5. Identify the field personnel responsible for verification/validation (by title, and organizational affiliation). Describe how verification/validation of field sampling, handling, and analysis activities will be documented (e.g., QC signatures in field logs, QC checklist, etc.). Describe which sampling, handling, field analytical, and fixed laboratory data will be verified/ validated internally and the data generator level. Describe the end product of laboratory verification (e.g., laboratory qualified data).

Describe which handling, field analytical, and fixed laboratory data will be verified/validated by entities external to the data generator. Identify external verification personnel (by title, and organizational affiliation) responsible for the project data verification.

A 100% laboratory data validation must be performed by an entity independent of the laboratory (i.e., engineering firm or laboratory's corporate QA officer), however, this validation may be done on hard copy data or performed electronically, if applicable (i.e., by CADRE).

The U.S. EPA Functional Guidelines are only directly applicable to Contract Laboratory Program Statements of Work, CLP-SOWs, low/medium analyses. For SW-846 and other analytical methods, this guidance document can be used to construct the validation procedures for these methods.

Each analytical report field and laboratory should be reviewed for compliance with the applicable method and for the quality of the data reported. The USEPA Contract Laboratory Program National Functional Guidelines for Inorganic Data Review, February 1994 and Functional Guidelines for Organic Data Review, October 1999 provide general data validation guidelines for the Superfund program. All additional data validation flags used for data should be identified.

The data validation procedure for all environmental measurements should be documented in the SOPs for each analytical procedure.

Identify the data validation personnel (by title, and organizational affiliation) that will be involved in the project.

INSTRUCTIONS for USABILITY/RECONCILIATION WITH DATA QUALITY
OBJECTIVES
Element D3

This element of the QAPP describes how the verified/validated project data will reconcile with the project data quality objectives, how data quality issues will be addressed, and how limitations on the use of the data will be reported and handled. This section describes the scientific and statistical procedures/methods that will be used to determine whether data are of the right type, quality and quantity to support environmental decision making for the project.

Note: Data quality assessment is the final step in data evaluation and can be performed on data of known and documented quality, which is verified/validated data.

Summarize the data assessment process and all data assessment procedures, including statistics, equations, and computer algorithms that will be used to assess data. Describe the data generation reporting formats and the documentation that will be generated during data assessment. Identify the personnel (by title, and organization affiliation) responsible for performing the data assessment.

A Formal Data Quality Assessment (DQA) Process is described in Guidance for the Data Quality Assessment: Practical Methods for Data Analysis (EPA QA/G-9). This document provides guidance on many statistical and graphical assessment tools. The Formal DQA Process consists of five steps:

1. Review DQOs and Sampling Design.
2. Conduct Preliminary Data Review.
3. Select Statistical Test.
4. Verify Assumptions.
5. Draw Conclusions from the Data.

Even if the Formal DQA Process is not followed in its entirety, a systematic assessment of the data quality must be performed. This process should include a preliminary data review. It is recommended that the QAPP include flow diagrams to describe the data quality assessment process for the project.

Describe how data will be presented in order to identify the trends, relationships (correlations), and anomalies.

Describe the evaluative procedures used to assess overall measurement error associated with the project and include the following:

A. Precision

In order to meet the need of the data users, project data must meet the measurement performance criteria for precision specified in Element A7B of the QAPP.

Project Precision (Field Duplicates/Replicates): Include/reference formulas to calculate precision for individual duplicate/replicated data points.

Analytical Precision (Laboratory Duplicate/Replicates, etc.): Include/reference the formulas for calculating analytical precision for individual duplicate/replicate data points.

Overall Precision: Describe the procedures used to perform overall assessment of precision in terms of the entire set of project data and include mathematical and/or statistical formulas for evaluating overall precision.

Poor overall precision may be the results of one or more of the following: field instrument variation, analytical measurement variation, poor sampling technique, sample transport problems, and/or heterogeneous matrices. In order to identify the cause of imprecision, the field sampling design rationale and sampling techniques should be evaluated by the reviewer and both field and analytical duplicate/replicate sample results should be reviewed. If poor precision is indicated in both the field and analytical duplicates/replicates, then the laboratory may be a source of the error. If poor precision is limited to the field duplicate/replicate results, then the sampling technique, field instrument variation, sample transport, and/or heterogeneous sample matrices may be a source of the error.

If the Data Validation Report indicates that analytical imprecision exists for a particular data set, then the impact of that imprecision on data usability must be discussed in the Data Assessment Report.

The Data Assessment Report should discuss and compare the overall field duplicate precision data from multiple data sets collected for the project for each matrix, analytical parameter and concentration level. Data Assessment Reports should describe the limitations on the use of project data when the overall precision is poor or when poor precision is limited to a specific sampling or laboratory/analytical group, data set, matrix, analytical parameter or concentration level.

When project-required precision is not achieved and project data are not usable to adequately address environmental questions (i.e., determining if regulatory/technical Action Limits have been exceeded) and to support project decision making, then the Data Assessment Report should address how this problem will be resolved and discuss the potential need for resampling.

B. Accuracy/Bias

In order to meet the needs of the data users, project data must meet the measurement performance criteria for accuracy/bias specified in Element A7B of the QAPP.

Sample contamination: Discuss how the QC activities and QC check sample data will be reviewed to evaluate the accuracy and potential bias of sample results. If field contamination exists, then the impact of field contamination on data usability must be discussed in the Data Assessment Report, and the Field Sampling Team Leader and Project Manager should be notified. Differentiate field sample collection and transport contamination (equipment/rinsate blanks, trip blanks) from contamination introduced at the time of sample preparation and/or analysis, (i.e., method blank, storage blank, analytical instrument blanks). Note that sample contamination may result in either negative or positive bias. For example, improperly cleaned sample containers for metals analysis may result in the retention of metals on interior container walls. This would result in lower metals concentration being reported than are actually present in the collected sample (i.e., negative bias). A positive bias would occur when sample container contamination results in additive effect, i.e., the reported analyte concentrations are higher than the true sample concentrations for that analyte.

Analytical Accuracy/Bias: Discuss how the QC activities and QC check and sample data will be used to evaluate the accuracy and potential bias of sample results. Include/reference formulas for calculating analytical accuracy and bias for spike samples/compounds (matrix spikes, surrogate spikes, laboratory control spikes, etc.), PE samples, calibration linearity, results of calibration verification checks, etc. If data Validation Reports indicate that contamination and/or analytical inaccuracies/bias exist for a particular data set, then the impact of that contamination and/or analytical inaccuracies/bias on data usability must be discussed in Data Assessment Report.

Overall Accuracy/Bias: Describe the procedures used to perform overall assessment of accuracy/bias in terms of the entire set of project data and include mathematical and/or statistical formulas for evaluating overall accuracy/bias. Describe the procedures for evaluating the overall qualitative and quantitative bias trends in PE samples' data.

The Data Assessment Report should discuss and compare overall contamination and accuracy/bias data from multiple data sets collected for the project for each matrix, analytical parameter and concentration level. The Data Assessment Report should describe the limitations on the use of the project data if extensive contamination and/or inaccuracy/bias exists or when it is limited to a specific sampling or laboratory analytical group, data set, matrix, analytical parameter or concentration level. The Data Assessment Report should identify qualitative and/or quantitative bias trends in multiple PE samples results for each matrix, analytical parameter and concentration level. The impact of any qualitative and/or quantitative trends in bias on the sample data should be discussed. **Any PE samples that have false positive and/or false negative results should be reported and the impact on data usability should be discussed in the Data Assessment Report.**

When project-required accuracy/bias is not achieved and project data are not usable to adequately address environmental questions (i.e., determining if regulatory/technical Action Limits have been exceeded) and to support project decision making, then the Data Assessment Report should address how this problem will be resolved and discuss the potential need for resampling.

C. *Sample Representativeness*

In order to meet the needs of the data users, project data must meet the measurement performance criteria for sample representativeness specified in Element A7B of the QAPP.

Discuss how the QA/QC activities (review of sampling SOPs, Field Sampling TSAs, Split Sampling and Analysis Audits, etc.) and QC check and sample data will be reviewed to assess sample representativeness. If field duplicate precision checks indicate potential spatial variability, then this may trigger additional scoping meetings and subsequent resampling in order to collect data that is more representative of a non-homogeneous site.

The Data Assessment Report should discuss and compare overall representativeness for each matrix, parameter and concentration level. Data Assessment Reports should describe the limitations on the use of project data when overall non-representative sampling has occurred or when non-representative sampling is limited to a specific sampling group, data set, matrix, analytical parameter or concentration level. If data are not usable to adequately address

environmental questions and/or support project decision making, then the Data Assessment Report should address how this problem will be resolved and discuss the potential need for resampling.

D. Sensitivity and Quantitation Limits

In order to meet the needs of the data user, project data must meet the measurement performance criteria for sensitivity specified in Element A7B.

Include formulas for calculating analytical sensitivity that ensure Quantitation Limits (QLs) are achieved, e.g., percent recovery of Laboratory Fortified Blank spiked compounds, and PE samples. Also, include procedures for evaluating low calibration standards run at QLs. Low point calibration standards should produce a signal at least ten times the background noise level and should be part of a linear calibration curve.

Document the procedures for calculating MDLs and QLs.

Overall Sensitivity and Quantitation Limits: Describe the procedures used to perform overall assessment and QLs in terms of the entire set of project data, and include mathematical and/or statistical formulas for evaluating sensitivity and QLs.

If Data Validation Reports indicate that sensitivity and/or QLs were not achieved, then the impact of that lack of sensitivity and/or higher QLs on data usability must be discussed in the Data Assessment Report.

The Data Assessment Report should discuss and compare overall sensitivity and QLs from multiple data sets collected for the project for each matrix, analytical parameter and concentration level. Data Assessment Reports should describe the limitations on the use of the project data if project-required sensitivity and QLs were not achieved for all project data or when it is limited to a specific sampling or laboratory/analytical group, data set, matrix, analytical parameter or concentration level.

When project-required QLs are not achieved and project data are not usable to adequately address environmental questions (i.e., determining if regulatory/technical Action Limits have been exceeded) and to support project decision making, then the Data Assessment Report should address how this problem will be resolved and discuss the potential need for resampling. In this case, the Data Assessment Report should clearly differentiate between usable and unusable data for the data users.

E. Completeness

In order to meet the needs of the data users, project data must meet the measurement performance criteria for data completeness specified in Element A7B of the QAPP.

Include the methods/formulas for calculating data completeness. Describe how the amount of valid data will be determined as a percentage of the number of valid measurements that should have been collected for each matrix, analytical parameter, and concentration level. When certain

sample locations and/or analytes and matrices are more critical than others in making project decisions, describe how critical data will be assessed for completeness.

Overall Completeness: Describe the procedures used to perform overall assessment of completeness in terms of the entire set of project data, and include mathematical and/or statistical formulas for evaluating overall completeness.

The Data Assessment Report should discuss and compare overall completeness of multiple data sets collected for the project for each matrix, analytical parameter and concentration level. Data Assessment Reports should describe the limitation on the use of the project data if project required completeness was not achieved for the overall project or when it is limited to a specific sampling or laboratory/analytical group, data set, matrix, analytical parameter or concentration level.

When project required completeness is not achieved and sufficient data are not available to adequately address environmental questions and support project decision making, then the Data Assessment Report should address how this problem will be resolved and discuss the potential need for additional resampling.

F. Comparability

In order to meet the needs of the data users, project data must meet the measurement performance criteria for comparability specified in Element A7B of the QAPP.

Include/reference formulas for assessing data comparability for each matrix, analytical parameter and concentration level.

If two or more sampling procedures and/or sampling teams will be used to collect samples, then describe how comparability will be assessed for each matrix, analytical parameter and concentration level.

If two or more analytical methods/SOPs will be used to analyze samples of the same matrix and concentration level for the same analytical parameter, then describe how comparability will be assessed between the two data sets.

If field screening data will be confirmed by full protocol methods, then document the specific method references and percent difference formula that will be used to assess comparability for individual data points (Refer to Element A7B).

Overall Comparability: Describe the procedures used to perform overall assessment of oversight split sampling comparability and include mathematical and/or statistical formulas for evaluating oversight split sampling data comparability.

For long term monitoring projects, data comparability is extremely important. Project data should be compared to previously generated data to determine the possibility of false positives and/or false negatives. Variations detected in the data may reflect a changing environment or indicate sampling and/or analytical error. Comparability criteria should be established to evaluate these

data sets in order to identify outliers and to trigger resampling.

The Data Assessment Report should discuss and compare overall comparability between multiple data sets collected for the project for each matrix, analytical parameter and concentration level. The Data Assessment Report should describe the limitation on the use of project data when project required data comparability is not achieved for the overall project or when it is limited to a specific sampling or laboratory/analytical group, data set, matrix, analytical parameter or concentration level.

If screen/confirmatory comparability criteria are not met, then this should be documented in the Data Assessment Report and the effect on data usability should be discussed. If oversight split sampling comparability criteria are not met, then this should be documented in the Data Assessment Report and the effect on data usability should be discussed. If data are not usable to adequately address environmental questions and/or support project decision making, then the Data Assessment Report should address how this problem will be resolved and discuss potential need for resampling.

Finally, if long-term monitoring data are not comparable, then the Data Assessment Report should address whether the data indicate a changing environment or whether the anomalies are a result of sampling and/or analytical error. If data are not usable to adequately address environmental questions and/or support project decision making, then the Data Assessment Report should address how this problem will be resolved and discuss potential need for resampling.

G. Data Limitations and Actions

Describe what actions will be taken when data do not meet the project quality objectives. It is necessary to document, in this section of the QAPP, the exact process for handling data that do not meet project quality objectives, i.e., when measurement performance criteria are not met. Depending on how those data will be used, the process should specify the restrictions on use of those data for environmental decision making.

Sources of sampling and analytical error should be identified and corrected as early as possible to the onset of sample collection activities. Incorporating an ongoing data assessment process during the project, rather than just as a final step, will facilitate the early detection and correction of problems, ensuring that project quality objectives are met.

ATTACHMENT A

QUALITY ASSURANCE PROJECT PLAN

FOR THE REMEDIAL INVESTIGATION/FEASIBILITY STUDY OR REMEDIAL
DESIGN/REMEDIAL ACTION [PROJECT TYPE (FUND-LEAD, ENFORCEMENT-LEAD)]
AT [SUPERFUND SITE NAME]

REVISION [NUMBER]

[DATE OF SUBMITTAL]

Prepared by: [Contractor Name]

[Contractor Project Manager]

Date

[Contractor QA Officer]

Date

[Laboratory QA Manager] (if applicable)

Date

State Project Manager (if applicable)

Date

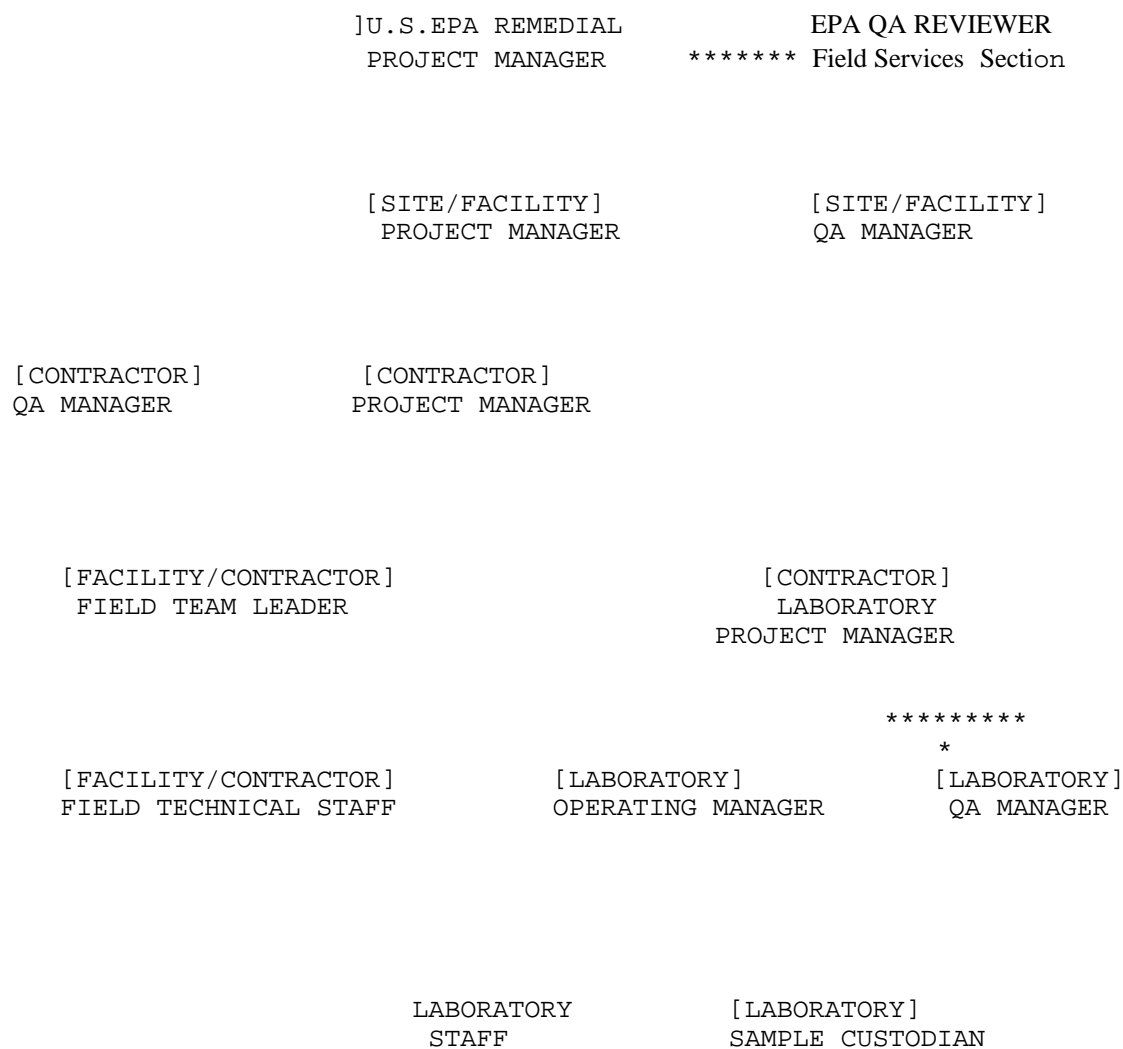
U.S. EPA Region 5 Remedial Project Manager

Date

U.S. EPA Region 5 Quality Assurance Reviewer

Date

FIGURE 1 SIGNATURE PAGE



LINE OF AUTHORITY

****LINE OF COMMUNICATION

FIGURE 2 PROJECT ORGANIZATION DIAGRAM

1. STATE THE PROBLEM
Summarize the contamination problem that will require new environmental data, and identify the resources available to resolve the problem.

2. IDENTIFY THE DECISION
Identify the information needed to support the decision, and data to address the contamination problem.

3. IDENTIFY INPUTS TO THE DECISION
Identify the information needed to support the decision, and specify which inputs require new environmental measurements.

4. DEFINE THE STUDY BOUNDARIES
Specify the spatial and temporal aspects of the environment media that the data must represent to support the decision.

5. DEVELOP A DECISION RULE
Develop a logical "if...then..." statement that defines the conditions that would cause the decision maker to choose among alternative actions.

6. SPECIFY LIMITS ON DECISION ERRORS
Specify decision makers' acceptable limits on decision errors, which is used to establish performance goals for limiting uncertainty in the data.

7. OPTIMIZE THE DESIGN FOR OBTAINING THE DATA
Identify the most resource-effective sampling and analysis design for generating data that are expected to satisfy the DQOs.

FIGURE 3. THE DATA QUALITY OBJECTIVES PROCESS

PROJECT SCHEDULE

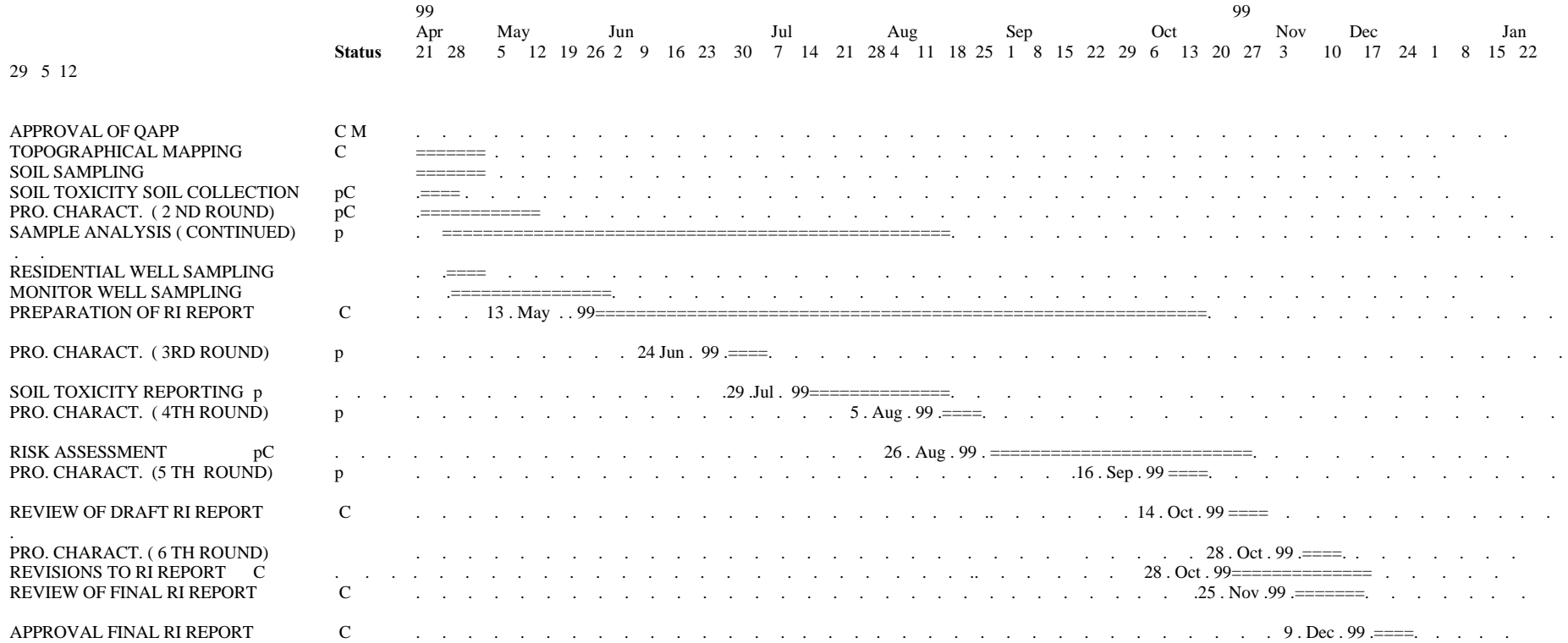


FIGURE 4

TABLE 1**VOA CONTAMINANTS OF CONCERN IN GROUND WATER SAMPLES**

Analyte	CAS Number	Project Action Limit (Units)	Project Quantitation Limits (Units)	Analytical Method MDLs	Achievable Laboratory MDLs
<i>Benzene</i>	<i>71-43-2</i>	<i>5 ug/l</i>	<i>1 ug/l</i>	<i>0.03 ug/l</i>	<i>0.10 ug/l</i>
<i>Trichloroethene</i>	<i>79-01-6</i>	<i>5 ug/l</i>	<i>1 ug/l</i>	<i>0.02 ug/l</i>	<i>0.11 ug/l</i>
<i>Vinyl Chloride</i>	<i>75-01-4</i>	<i>5 ug/l</i>	<i>1 ug/l</i>	<i>0.04 ug/l</i>	<i>0.11 ug/l</i>
<i>1,2-Dichloroethane</i>	<i>107-06-2</i>	<i>5 ug/l</i>	<i>1 ug/l</i>	<i>0.02 ug/l</i>	<i>0.11 ug/l</i>
<i>Carbon Tetrachloride</i>	<i>56-23-5</i>	<i>5 ug/l</i>	<i>1 ug/l</i>	<i>0.08 ug/l</i>	<i>0.12 ug/l</i>
<i>1,2-Dichloropropane</i>	<i>78-87-5</i>	<i>5 ug/l</i>	<i>1 ug/l</i>	<i>0.02 ug/l</i>	<i>0.11 ug/l</i>
<i>1,1,2-Trichloroethane</i>	<i>79-00-5</i>	<i>5 ug/l</i>	<i>1 ug/l</i>	<i>0.03 ug/l</i>	<i>0.13 ug/l</i>
<i>Bromoform</i>	<i>75-25-2</i>	<i>5 ug/l</i>	<i>1 ug/l</i>	<i>0.20 ug/l</i>	<i>0.11 ug/l</i>

TABLE 2

SUMMARY TABLE OF SAMPLING AND ANALYSIS PROGRAM Page: 1 of 1

<u>SAMPLE MATRIX</u>	<u>FIELD PARAMETERS</u>	<u>LABORATORY PARAMETERS</u>	<u>Sample No.</u>	<u>Field Duplicate</u>	<u>Field Blanks</u>	<u>MS/MSD^{2,3}</u>	<u>Matrix⁴</u>
Groundwater	pH, temperature	CLP TCL volatile organics	25	3	3	2	31
Phase 1, Round 1	Specific conductance	CLP Semivolatiles		25	3	3	2
	Organic vapor screening with HNu Slug Test	CLP TCL pesticides/PCBs	25	3	3	2	31
		CLP TAL Metals (filtered)	25	3	3	-	31
		CLP TAL cyanide (total)	25	3	3	-	31
		TKN, Ammonia-N, TOC	13	2	2	-	17
		COD, BOD,	6	1	1	-	8
Surface water	pH, temperature specific conductance	NO ₃ , NO ₂	13	2	2	-	17
		CLP TCL volatile organics	17	2	2	1	21
		CLP TCL Semivolatiles	17	2	2	1	21
		CLP TCL pesticides/PCBs	17	2	2	1	21
		CLP TAL metals(unfiltered)	17	2	2	-	21
		CLP TAL Cyanide (total)	17	2	2	-	21
Surface Soils	Soil gas screening using HNu/OVA	COD, BOD	9	1	1	-	11
		CLP TCL volatile organics	35	4	-	-	39
		CLP TCL Semivolatiles	35	4	-	-	39
		CLP TCL pesticides/PCBs	35	4	-	-	39
		CLP TAL metals	35	4	-	-	39
		CLP TAL cyanide	35	4	-	-	39

1. The field quality control samples also include trip blank, which is required for VOA water and air samples. One trip blank, which consists of two preserved 40-ml glass vials for water samples and one blank cartridge for air samples, is shipped with each shipping cooler of VOA samples.

2. Additional volume for Matrix spike/matrix spike duplicate (MS/MSD) is required for organic water analysis. Samples designated for MS/MSD analysis will be collected with extra sample volumes, at a frequency of one per group of 20 or fewer investigative samples. Triple the normal sample volumes will be collected for VOAs, and double the normal sample volumes will be collected for semivolatiles organics, pesticides and PCBs.

3. For inorganic analysis, no extra sample volume is required.

4. The number of samples to be collected for MS/MSD is not included in the matrix total. The number of trip blank samples is also excluded from the matrix total.

TABLE 3

DQO STEPS FOR THE BACKGROUND GROUNDWATER STUDY

STEP 1	STEP 2	STEP 3	STEP 4	STEP 5	STEP 6	STEP 7
STATE THE PROBLEM	IDENTIFY THE DECISIONS	IDENTIFY INPUTS TO THE DECISIONS	DEFINE STUDY BOUNDARIES	DEVELOP DECISION RULES	SPECIFY LIMITS ON DECISION ERRORS	OPTIMIZE SAMPLING DESIGN
<ul style="list-style-type: none"> •A defensible data set of the background concentrations of naturally occurring metals is needed, in order to perform comparisons of site and background data and determine the amounts of these naturally occurring metals that may have been introduced into the environment as a result of site activities. • Background data may also be used to set realistic cleanup standards for sites that may undergo future remediation. 	<ul style="list-style-type: none"> •Do concentrations of naturally occurring metals in shallow groundwater at the site exceed those of background? •What are realistic cleanup levels for sites that may undergo future remediation? 	<ul style="list-style-type: none"> •Validated defensible chemical data for shallow groundwater from areas not affected by site activities. •Analytical data for metals and water quality parameters in shallow groundwater from background area needs to be compiled and statistically evaluated. 	<ul style="list-style-type: none"> •Groundwater from the shallow aquifer will be sampled and analyzed. The shallow aquifer is unconfined to semi-confined within the study area. •Groundwater samples will be collected from areas predetermined to be located up gradient or side-gradient and away from the sites or far down-gradient from sites. •Samples will be collected each quarter for one year. Data for all 4 quarters will be composite for statistical analysis. 	<ul style="list-style-type: none"> •If comparison of site and background data sets shows statistically significant differences in the concentrations of the naturally occurring metals between background and site data sets, then, pending professional judgement, it may be assumed that site activities have affected the quality of shallow groundwater at the site. •If statistical comparison shows no significant differences, or the results are found not practically significant based on professional judgement, then no groundwater remediation of the site is necessary. 	<p>Statistical comparisons of site and background data populations will use a specified significance level, to be agreed to by the regulatory agencies.</p> <ul style="list-style-type: none"> •Professional judgement will be used to determine practical vs. Statistical significance of test results (see EPA 1998). 	<ul style="list-style-type: none"> •Background conditions will be determined for a sample population. Sample size was based on the analysis of existing data for 90-percent confidence level. •One year of quarterly groundwater samples will be collected from 18 monitoring wells screened in the shallow aquifer and located in background areas.

Notes:

DQO Steps = Data Quality Objective steps, as outlined by EPA in “Guidance for the Data Quality Objectives Process” EPA 1994. EPA QA/G-4. September.

TABLE 4

QA OBJECTIVES FOR FIELD MEASUREMENTS

PARAMETER	METHOD ⁽¹⁾ REFERENCE	PRECISION ⁽²⁾	ACCURACY ⁽³⁾	COMPLETENESS
WATER				
Standing Water Levels	Solinst Water Level Indicator	±0.01 ft.	0.005 ft.	95%
Temperature	E170., Mercury Thermometer or Electronic Temperature Probe	±0.5°C	1.0°C	95%
Conductivity	E120.1, Electrometric	±25	10 umho/cm ²	95%
pH	E150.1, Electrometric	±0.1 pH units	0.05 pH units	95%
Turbidity	E180.1	10 NTU ⁽⁴⁾	0.5 NTU ⁽⁴⁾	95%
Redox Potential	ASTM 1498-93	±10mV	10 mV	95%
Dissolved Oxygen	SM-A4500	±0.05 mg/L	±0.1 mg/L	95%
SOIL				
Bulk Density	ASTM D-1556	NPM	NPM	95%
Soil pH	SW-9045	±0.1 pH units	0.05 pH units	95%

NOTES:

1. Methods: E - *Method for Chemical Analysis for Water and Wastes* (U.S. EPA, 1983).
SW - *Test for the Evaluation of Solid Waste*, SW-846, U.S. EPA, September 1986, Update III, June 1997.
SM - *Standard Methods for Examination of the Water and Wastewater*, 18th ed. (APHA, 1992).
ASTM - *Annual Book of ASTM Standards*, American Society of Testing and Materials, 1995.
2. Expressed as the acceptable deviation from the Scale.
3. Expected based on equipment manufacturer specifications.
4. Acceptable accuracy and precision based on the range of measured. NTUs(nephelometric turbidity units). NPM - Not Part of Method

TABLE 5
QA OBJECTIVES FOR LABORATORY PARAMETERS

Matrix Spike Recovery and Relative Percent Difference Limits (RPD)				
	%Recovery		%RPD	
	Water	Soil	Water	Soil
Volatile Organic Compounds				
1,1-Dichloroethene	61-145	59-173	14	22
Trichloroethene	71-120	62-137	14	23
Benzene	76-127	66-142	11	21
Toluene	76-125	59-139	13	21
Chlorobenzene	75-130	60-133	13	21
Pesticides/PCBs				
γ-BHC (Lindane)	56-123	46-127	15	50
Heptachlor	40-131	35-130	20	31
Aldrin	40-120	34-132	22	43
Dieldrin	52-126	31-134	18	38
Endrin	56-121	42-139	21	45
4,4 ¹ -DDT	38-127	23-134	27	50
Semivolatile Organic Compounds				
Phenol	12-110	26-90	42	35
2-Chlorophenol	27-123	25-102	40	50
1,4-Dichlorobenzene	36-97	28-104	28	27
N-Nitroso-di-N-propylamine	41-116	41-126	38	38
1,2,4-Trichlorobenzene	39-98	38-107	28	23
4-Chloro-3-Methylphenol	23-97	26-103	42	33
Acenaphthene	46-118	31-137	31	19
4-Nitrophenol	10-80	11-114	50	50
2,4-Dinitrotoluene	24-96	28-89	38	47
Pentachloropheneol	9-103	17-109	50	47
Pyrene	26-127	35-142	31	36

TABLE 6
PREVENTATIVE MAINTENANCE

INSTRUMENTS	MAINTENANCE PROCEDURES/SCHEDULE	SPARE PARTS IN
Photovac MicroTIP Photoionization Detector	<ol style="list-style-type: none"> 1. Calibrate beginning and end of each day and as necessary during use. 2. Check battery, and recharge when low. 3. Clean lamp window every 24 hours of operation. 4. Replace dust filter every 240 hours of operation. 5. Replace sample pump every 5000 hours of operation. 	<ol style="list-style-type: none"> 1. Battery charger 2. Spare lamps 3. Spare filter cartridges
Thermo Environmental Model 580B Photoionization Detector	<ol style="list-style-type: none"> 1. Calibrate beginning and end of each day, and as necessary during use. 2. Check battery, and recharge when low. 3. Clean lamp and dust filter as needed. 4. Replace water traps if they become wet. 	<ol style="list-style-type: none"> 1. Spare lamps 2. Spare dust filters.
Field Gas Chromatograph	<ol style="list-style-type: none"> 1. Change injector septa daily. 2. Repack column when separation and linearity becomes poor. 3. Clean PID lamp before each initial calibration; change when sensitivity lost. 4. Clean injector port/liner weekly. 	<ol style="list-style-type: none"> 1. Septa 2. Empty columns and column packing 3. PID lamps 4. Injector lines
pH Meter	<ol style="list-style-type: none"> 1. Calibrate beginning and end of each day, and as necessary during use. 2. Replace electrodes as needed. 	<ol style="list-style-type: none"> 1. pH buffers 2. Batteries 3. Spare electrodes
Conductivity Meter	<ol style="list-style-type: none"> 1. Calibrate beginning and end of each day, and as necessary during use. 2. Check redline and replace batteries if does not calibrate. 	<ol style="list-style-type: none"> 1. Batteries
HNu Model Photoionization Detector	<ol style="list-style-type: none"> 1. Calibrate beginning and end of each day, and as necessary during use. 2. Check battery, and recharge when low. 3. Clean UV lamp, ion chamber, and fan if calibration falls outside 10% of the calibration standard, or if readings are erratic. 	<ol style="list-style-type: none"> 1. Battery charger 2. Spare lamps

TABLE 7

SAMPLE CONTAINER,PRESERVATION AND HOLDING TIME REQUIREMENTS

MATRIX	ANALYSIS	CONTAINER	PRESERVATION	HOLDING TIME
SOIL/SEDIMENT	METALS	1-8 OZ WM GLASS JAR	COOL TO 4°C	6 MONTHS, MERCURY 28 DAYS
	CYANIDE	1-8 OZ WM GLASS JAR	COOL TO 4°C	14 DAYS
	VOLATILES	2-120 ml WM MOUTH GLASS VIALS/En CORE/ 3-40 ml WMMOUTH GLASS VIALS	COOL TO 4°C NO Headspace 5-10 ml Methanol	14 DAYS/48 HOURS/14 DAYS
	SEMIVOLATILES	1-8 OZ WM AMBER GLASS JAR	COOL TO 4°C	14 DAYS UNTIL EXTRACTION, 40 DAYS AFTER EXTRACTION
	PEST/PCBs	1-8 OZ WM AMBER GLASS JAR	COOL TO 4°C	14 DAYS UNTIL EXTRACTION, 40 DAYS AFTER EXTRACTION
	TOTAL ORGANIC CARBON	1-4 OZ WM GLASS JAR	COOL TO 4°C	28 DAYS
WATER	VOLATILES	TWO 40-ml SEPTUM CAP VIALS	HCL TO pH<2, COOL TO 4°C	14 DAYS
	SEMIVOLATILES	2-1 LITER AMBER GLASS BOTTLE WITH TEFLON LINER	COOL TO 4°C	7 DAYS UNTIL EXTRACTION, 40 DAYS AFTER EXTRACTION
	PEST/PCB	2-1 LITER AMBER GLASS BOTTLE WITH TEFLON LINER	COOL 4°C	7 DAYS UNTIL EXTRACTION, 40 DAYS AFTER EXTRACTION
	METALS	1-1 LITER POLYETHYLENE BOTTLE	HNO ₃ TO pH<2	6 MONTHS, MERCURY 28 DAYS
	CYANIDE	1-1 LITER POLYETHYLENE BOTTLE	NaOH TO pH>12, COOL 4°C	14 DAYS
	ALKALINITY	1-1 LITER POLYETHYLENE BOTTLE	COOL TO 4°C	14 DAYS
	NITRATE/NITRITE	1-250 mL POLYETHYLENE BOTTLE	COOL TO 4°C, H ₂ SO ₄ TO pH<2	28 DAYS
	TOTAL DISSOLVED SOLIDS	1-250 mL POLYETHYLENE BOTTLE	COOL TO 4°C	7 DAYS
	TOTAL SUSPENDED SOLIDS	1-250 mL POLYETHYLENE BOTTLE	COOL TO 4°C	7 DAYS
	TOTAL KJELDAHL NITROGEN	1-500 mL POLYETHYLENE BOTTLE	H ₂ SO ₄ TO pH<2, COOL TO 4°C	28 DAYS

TABLE 8

PREVENTIVE MAINTENANCE FOR ANALYTICAL INSTRUMENTS

<u>INSTRUMENT</u>	<u>ACTIVITY</u>	<u>FREQUENCY</u>
Gas Chromatograph/ Mass Spectrometer Check	Change septum	Monthly/as needed
	carrier gas	Daily
	Change carrier gas	When pressure reaches 100 psi
	Change gas filters	Semi-annually/as needed
	Change trap on Tekmar	As needed/poor sensitivity
	Change GC column	As needed/poor sensitivity
	Clean MS source	As needed/poor sensitivity
	Check pump of leaks	Monthly
	Leak Check septum	As needed/when leak suspected
	Check gas flow	As needed
	Clean VOA purge	
	glassware	As needed
	Cut capillary column	As needed
	Replace liner	As needed/contamination susp.
	Replace BNA seal	As needed/contamination susp.
Lachat Qulchem AE	Dry and clean random	
	access sampler	Daily
	Clean sample boats	Daily
	Coat rollers of pump	
	with silicone spray	Every 2500 samples
	Replace pump tubes	Monthly
	Replace flames at	
	port of valve module	Every 25000 samples
	Clean unions of	
	the valve	Every 25000 samples
	Replace O-rings	When necessary
TOC	Clean each port	
	of the valve	Weekly
	Clean fitting of	
	manifolds	Every 25000 samples
TOC	Replace water in IC Chamber	Weekly
	Clean IC chamber	As needed
	Clean underside of IC Inlet	
	valve	As needed
	Check combustion tube	Daily
	Repack quartz wool in	
	comb. tube	As needed
	Check TC inlet valve	Daily
	Clean TC inlet valve	As needed
	Refill acid bottle	When 2/3 empty
GPC	Change seals and oil	
	motor on positive	Ever 1500-2000 hours of use
	displacement pump	
	Repack column	When column flow is restricted or operating pressure increases
	Check system pressure	Check daily when operating
	Replace mesh at column	Replace if torn or wrinkled
	effluent/influent	
GPC	Check calibration, pressure	
	and solvent flow	Check weekly

Table 8 (Continue)

PREVENTIVE MAINTENANCE FOR ANALYTICAL INSTRUMENTS

<u>INSTRUMENT</u>	<u>ACTIVITY</u>	<u>FREQUENCY</u>
Atomic Absorption	Clean furnace windows	Daily
Atomic Absorption Furnace	Clean furnace windows	Daily
	Check plumbing connections	Daily
	Change graphite tube	As needed
	Check gases	Daily
	Check autosampler and tubing	Daily
ICAP	Clean filters	Monthly
	Check gas flow	Daily
Furnace	Change tubing	Weekly
	Clean nebulizer	As needed
	Check autosampler and tubing	Daily
Gas Chromatograph- Volatiles	Check Hall propanol flow	Daily
	Check Hall furnace temp.	Daily
	Check PID sensitivity	Daily
	Change lamp	As needed
	Rinse purge devices	Daily
	Bake purge devices	Daily
	Check carrier gases	Daily
	Change carrier gases	As needed
	Check column flows	Daily
	Check for gas leaks	At each column change
	Replenish electrolytic conductivity detector solvents	As needed
	Clean transfer lines	As needed
Gas Chromatograph- Semivolatiles	Change septum	Every 100 shots or as needed
	Check carrier gas	Daily
	Change carrier gas	When pressure reaches 250 psi
	Change in-line filters	Every 6 mos. or as needed
	Remove first foot of capillary column	As needed
	Clean ECD	As needed
	Clean Nitrogen-Phosphorous Detector	As needed
	Check system for gas leaks	At each column change
	Replace column	As needed
	Clean FID	As needed
	Replace capillary injection port liner	At column change or as needed
	Replace capillary injection port seal	As column change or as needed
	Measure gas flow	After changing column
	Check syringe	Daily

ATTACHMENT B

QAPP REVIEW CHECK LIST

ELEMENT		COMMENTS
A1.	Title and Approval Sheet	
	Title	
	Organization's name	
	Dated signature of project manager	
	Dated signature of quality assurance officer	
	Other signatures, as needed	
A2.	Table of Contents	
A3.	Distribution List	
A4.	Project/Task Organization	
	Identifies key individuals, with their responsibilities (data users, decision-makers, project QA manager, subcontractors, etc.)	
	Organization chart shows lines of authority and reporting responsibilities	
A5.	Problem Definition/Background	
	Clearly states problem or decision to be resolved	
	Provides historical and background information	
A6.	Project/Task Description	
	Lists measurements to be made	
	Cites applicable technical, regulatory, or program-specific quality standards, criteria, or objectives	
	Notes special personnel or equipment requirements	
	Provides work schedule	
	Notes required project and QA records/reports	
A7.	Quality Objectives and Criteria for Measurement Data	
	States project objectives and limits, both qualitatively and quantitatively	
	States and characterizes measurement quality objectives as to applicable action level criteria	
A8.	Special Training Requirements .Certification Listed	
	States how provided, documented, and assured	
A9.	Documentation and Records	
	List information and records to be included in data report (e.g., raw data, field logs, results of QC checks, problems encountered)	
	States requested lab turnaround time	
	Gives retention time and location for records and reports	

QAPP REVIEW CHECK LIST (CONTINUED)

ELEMENT		COMMENTS
B1.	Sampling Process Design (Experimental Design) States the following:	
	Type and number of samples required	
	Sampling design and rationale	
	Sampling location and frequency	
	Sample matrices	
	Classification of each measurement parameter as either critical or needed for information only	
	Appropriate validation study information, for nonstandard situations	
B2.	Sampling Methods Requirements	
	Identifies sample collection procedures and methods	
	List equipments needs	
	Identifies support facilities	
	Identifies individuals responsible for corrective action	
	Describes process for preparation and decontamination of sampling equipment	
	Describes selection and preparation of sample containers and sample volumes	
	Describes preservation methods and maximum holding times	
B3.	Sample Handling and Custody Requirements	
	Notes sample handling requirements	
	Notes chain-of-custody procedures, if required	
B4.	Analytical Method Requirements	
	Identifies analytical methods to be followed (with all options) and required equipment	
	Provides validation information for nonstandard methods	
	Identifies individuals responsible for corrective action	
	Specifies needed laboratory turnaround time	
B5.	Quality Control Requirements	
	Identifies QC procedures and frequency for each sampling, analysis, or measurement technique, as well as associate acceptance criteria and corrective action	
	References procedures used to calculate QC statistics including precision and bias/accuracy	
B6.	Instrument/Equipment Testing, Inspection and Maintenance Requirements	
	Identifies acceptance testing of sampling and measurement systems	
	Describes equipment preventive and corrective maintenance	

QAPP REVIEW CHECK LIST (CONTINUED)

ELEMENT		COMMENTS
	Notes availability and location of spare parts	
B7.	Instrument Calibration and Frequency	
	Identifies equipment needing calibration and frequency for such calibration	
	Notes required calibration standards and/or equipment	
	Cites calibration records and manner traceable to equipment	
B8.	Inspection Acceptance Requirements for Supplies and Consumables	
	States acceptance criteria for supplies and consumables	
	Notes responsible individuals	
B.9	Data Acquisition Requirements for Nondirect Measurements	
	Identifies type of data needed from nonmeasurement sources (e.g., computer data base and literature files, along with acceptable criteria for their use	
	Describes any limitations of such data	
	Documents rationale for original collection of data and its relevance to this project	
B10.	Data Management	
	Describes standard record-keeping and data storage and retrieval requirements	
	Checklists or standard forms attached to QAPP	
	Describes data handling equipment and procedures used to process, compile, and analyze data (e.g., required computer hardware and software)	
	Describe process for assuring that applicable Office of Information Resource Management requirements are satisfied	
C1.	Assessment and Response Actions	
	Lists required number, frequency and type of assessments, with approximate dates and names of responsible personnel (assessments include but are not limited to peer reviews, management systems reviews, technical systems audits, performance evaluations, and audits of data quality)	
	Identifies individuals responsible for corrective actions	
C2.	Reports to Management Identifies frequency and distribution of reports for:	
	Project status	
	Results of performance evaluations and audits	
	Results of periodic data quality assessments	
	Any significant QA problems	
	Preparers and recipients of reports	

QAPP REVIEW CHECK LIST (CONTINUED)

ELEMENT		COMMENTS
D1.	Data Review, Validation, and Verification Methods	
	States criteria for accepting, rejecting, or qualifying data	
	Includes project-specific calculations or algorithms	
D2.	Validation and Verification Methods	
	Describes process for data validation and verification	
	Identifies issue resolution procedure and responsible individuals	
	Identifies method for conveying these results to data users	
D3.	Reconciliation with User Requirements	
	Describe process for reconciling project results with DQOs and reporting limitations on use of data	

CROSSWALK BETWEEN EPA QA/R-5 AND QAMS-005/80

QAMS 005/80 ELEMENTS	QA/R-5 ELEMENTS
1. Title Page with Provision for Approval Signatures	A1 Title and Approval Sheet
2. Table of Contents	A2 Table of Contents
3. Project Description	A5 Problem Definition A6 Project/Task Description
4. Project Organization and Responsibility	A4 Project/Task Organization A9 Documentation and Records
5. QA Objectives for Measurement Data (PARCC)	A7 Quality Objectives and Criteria for Measurement Data
6. Sampling Procedures	B1 Sampling Process Design B2 Sampling Methods Requirements
7. Sample Custody	A8 Special Training Requirements or Certificates B3 Sample Handling and Custody Requirements
8. Calibration Procedures and Frequency	B7 Instrument Calibration and Frequency
9. Analytical Procedures	B4 Analytical Methods Requirements
10. Data Reduction, Validation, and Reporting	D1 Data Review, Validation, and verification Requirements D2 Validation and Verification Methods B9 Data Acquisition Requirements B10 Data Quality Management
11. Internal Quality Control Checks and Frequency	B5 Quality Control Requirements
12. Performance and System	C1 Assessments and Responsible Action
13. Preventive Maintenance	B6 Instrument/Equipment Testing, Procedures and Schedules Inspection, and Maintenance Requirements B8 Inspection/Acceptance Requirements for Supplies and Consumables
14. Specific Routine Procedures Measurement Parameters Involved	D3 Reconciliation with Data Used to Assess PARCC for Quality Objectives Measurement
15. Corrective Action	C1 Assessments and Response Action
16. QA Reports to Management	A3 Distribution List C2 Reports to Management

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5**

DATE:

SUBJECT: QAPP REVIEW REQUEST

FROM: _____ **RPM, PHONE:** _____

**TO: STEVE OSTRODKA, CHIEF
FIELD SERVICES SECTION**

Attached please find ___ copies of a QAPP for your review.

SITE NAME: _____ **STATE:** _____

LEAD: FUND _____ **PRP** _____ **STATE** _____

SITE ACCOUNT# _____

PHASE/STAGE: RI/FS, RD, RA **OTHER** _____

QAPP REVISION NO.: _____ *(INITIAL REV. IS '0')*

QAPP PREPARED BY: _____, **PHONE:** _____

(CONTRACTOR)

PRE-QAPP MEETING? YES/NO **MTG. DATE:** _____

REQUESTED REVIEW TIME:

___ **INITIAL REVISION, UP TO 21 DAYS**

___ **1ST REVISION, UP TO 14 DAYS**

___ **2ND REVISION, ADDENDUMS, ETC. 07 DAYS***

EXPEDITED REVIEWS WILL NEED A MEMO FROM BRANCH CHIEF

ENCLOSURE/OTHER DOCUMENTS:

___ **WORKPLAN** ___ **SAMPLING PLAN** ___ **SOPs** ___ **SAS**

COMMENTS: _____

TO BE FILLED IN BY FSS: **DATE IN:** _____

DATE DUE: _____

FSS LOG-IN NO.: _____

****TURNAROUND TIMES OF 7 DAYS OR LESS WILL BE DETERMINED ON WORKLOADS, DEADLINES OR OTHER CONSTRAINTS ON RPM OR FSS REVIEWER.***